NUTRA HARMONY LLC

Final Clinical Study Report

A 3-Month, Randomized, Single-Blind, Placebo-Controlled Study Evaluating the Ability of Nutra Harmony "Biotin, Collagen & Keratin Beauty Complex" Dietary Supplement Promotion in Hair Thickness and Hair Strength in Individuals with Self-Perceived Thinning Hair

PRINCIPAL INVESTIGATOR: Prof. Olga Gyrina, Limited Liability Company Treatment and Diagnostic Center ADONIS Plus, Outpatient Department, 8B, Raisy Okipnoi St., Kyiv 02002, Ukraine

DATE STUDY INITIATED:19 February 2024

(Date first subject signed informed consent)

DATE STUDY COMPLETED: 12 July 2024

(Date when the last study-related procedure was performed)

Date: 30 August 2024
Prepared by: NUTRA HARMONY LLC

GCP Compliance: This study was conducted in compliance with Good Clinical Practice.

Confidentiality Statement

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you that is indicated as privileged or confidential.

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Version of Protocol	1.0 from 06 Feb 2024
We, the undersigned, have read this final study report and hereby certify that the study was conducted in accordance with the requirements of the Protocol and the presented research results are true and reliable.	
Sponsor	NUTRA HARMONY LLC 312 W 2nd St., Office 5161, Casper, WY 82601 +1 – 855 - 505 - 0012
Sponsor's responsible person	_____
Study Center	Limited Liability Company Treatment and Diagnostic Center ADONIS Plus, Outpatient Department, 8B, Raisy Okipnoi St., Kyiv 02002, Ukraine
Principal Investigator	_____ Prof. Olga Gyrina

SYNOPSIS

Name of Sponsor/Company: NUTRA HARMONY LLC

Title:	A 3-Month, Randomized, Single-Blind, Placebo-Controlled Study Evaluating the Ability of Nutra Harmony "Biotin, Collagen & Keratin Beauty Complex" Dietary Supplement Promotion in Hair Thickness and Hair Strength in Individuals with Self-Perceived Thinning Hair.
Study Description:	The Nutra Harmony "Biotin, Collagen & Keratin Beauty Complex" is an oral food/dietary supplement specifically designed to promote hair growth for people suffering from temporary thinning hair. The hypothesis of this clinical research study is that the ingestion of "Biotin, Collagen & Keratin Beauty Complex" for over a three (3) month period will strengthen the hair and increase hair thickness by promoting the growth of terminal hairs in subjects, ages 21-45 years of age with self-perceived thinning hair associated with poor diet, stress, hormonal influences when compared to using the placebo tablet.
Objectives:	The objective of this single-blind, placebo-controlled study is to assess the ability of Nutra Harmony "Biotin vitamins with collagen & keratin" to promote the growth of terminal hairs in adults with self-perceived thinning hair.
Endpoints:	The primary endpoints are to establish a significant increase in hair growth in study supplement-treated subjects which will be defined by determining the change in hair area from the baseline and counting the amount of hair in several control points from the baseline comparing to placebo-treated subjects. The secondary endpoints of the study are determined by hair washing (shampooing) for hair shedding counts in study supplement-treated subjects comparing to placebo-treated subjects and the change in patient quality of life questionnaires and self-assessment questionnaires following treatment.
Study Population:	Individuals, ages 21-50 years of age
Phase:	N/A
Description of Study Intervention:	"Biotin, Collagen & Keratin Beauty Complex" 30,000 mcg, 60 capsules, oral route of administration. Placebo (microcrystalline cellulose (MCC)), 60 capsules, oral route of administration
Study Duration:	3 months

RESUME

This report presents the materials of the clinical study “A 3-Month, Randomized, Single-Blind, Placebo-Controlled Study Evaluating the Ability of Nutra Harmony “Biotin, Collagen & Keratin Beauty Complex” Dietary Supplement Promotion in Hair Thickness and Hair Strength in Individuals with Self-Perceived Thinning Hair.”

The clinical trial was conducted in order to assess the ability of the studied “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules produced by NUTRA HARMONY LLC compared to placebo (microcrystalline cellulose (MCC)), 60 capsules manufactured by NUTRA HARMONY LLC.

The clinical study was conducted on the basis of the outpatient department of Adonis Plus Medical Diagnostic Center LLC. 80 patients with self-perceived thinning hair were included as study subjects. Based on the method of simple randomization, patients were divided into the main group - 40 patients and the control group - 40 patients in a ratio of 1:1. Patients of the main group were prescribed the “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules produced by NUTRA HARMONY LLC, patients of the control group were prescribed placebo (microcrystalline cellulose (MCC)), 60 capsules manufactured by NUTRA HARMONY LLC. The duration of study in both groups of subjects was 3 months (90 days).

The effectiveness of the treatment was evaluated by considering the increase in hair growth in study supplement-treated subjects, which was defined by determining the change in hair area from the baseline and counting the amount of hair in several control points from the baseline comparing to placebo-treated subjects, as well as hair washing (shampooing) for hair shedding counts in study supplement-treated subjects comparing to placebo-treated subjects and the change in patient quality of life questionnaires and self-assessment questionnaires during and following the study.

The tolerability of the studied supplement was assessed on the basis of the patient's subjective complaints, the presence and severity of adverse reactions/side effects, the data of the patient's hair examination and laboratory examination.

According to the results of the study, the supplement was found to be effective for subjects who were receiving “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules produced by NUTRA HARMONY LLC, compared to placebo (microcrystalline cellulose (MCC)), 60 capsules manufactured by NUTRA HARMONY LLC

The study supplement “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules produced by NUTRA HARMONY LLC was well tolerated by study participants and did not cause serious adverse reactions. The study supplement was well tolerated by participants.

The report contains: 37 pages, 16 tables and 8 sources of domestic and foreign literature.

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
CONSORT	Consolidated Standards of Reporting Trials
EC	Ethics Committee
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonization
IRB	Institutional Review Board
PI	Principal Investigator
SAE	Serious Adverse Event
SOA	Schedule of Activities
SOP	Standard Operating Procedure

ETHICS

Independent Ethics Committee/Institutional Review Board

The study protocol and amendments were reviewed by a Local Ethics Committee of Limited Liability Company Treatment and Diagnostic Center ADONIS Plus, Outpatient Department.

Ethical Conduct of the Study

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki, the Law of Ukraine "On Medicinal Products", orders of the Ministry of Health of Ukraine No. 95 and 690, in compliance with the principles of Good Clinical Practice (GCP) and in strict accordance with the Study Protocol. Known instances of nonconformance were documented and are not considered to have had an impact on the overall conclusions of this study.

Subject Information and Consent

Subjects provided their written consent to participate in the study after having been informed about the nature and purpose of the study, participation/termination conditions, and risks and benefits of treatment. Known instances of nonconformance were documented and are not considered to have impacted the overall conclusions of this study.

Subjects were informed that in case of violation of their rights during clinical research, they can apply to the Local Ethics Committee.

The principal investigator (PI) and the Sponsor ensured the protection of personal data of the subjects participating in the study. Personal data from subjects enrolled in this study were limited to those data necessary to investigate the efficacy, safety, quality, and utility of the investigational study agent(s) used in this study and were collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.

INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Principal Investigator:	Prof. Olga Gyrina
Study Center:	Limited Liability Company Treatment and Diagnostic Center ADONIS Plus, Outpatient Department, 8B, Raisy Okipnoi St., Kyiv 02002, Ukraine
Sponsor:	NUTRA HARMONY LLC 312 W 2nd St., Office 5161, Casper, WY 82601 +1 – 855 - 505 - 0012
Sponsor's Responsible:	
Local Ethics Committee:	Local Ethics Committee of Limited Liability Company Treatment and Diagnostic Center ADONIS Plus, Outpatient Department, 8B, Raisy Okipnoi St., Kyiv 02002, Ukraine

INTRODUCTION

Hair loss in women and men is often an overlooked and underappreciated condition. Reasons for pattern hair loss include medical conditions, medications, and physiologic or emotional stress. But one of the most common causes may surprise you: nutrition. Nutritional deficiencies may include inadequate intake of proteins, minerals, essential fatty acids, and vitamins. So, a nutritional intervention may be beneficial for patients with hair loss. Recent evidence suggested that the used of nutritional supplementation among patients with hair loss disorders is prevalent.
The study supplement "Biotin, Collagen & Keratin Beauty Complex" is an oral food/dietary supplement specifically designed to promote hair growth for people suffering from temporary thinning hair.
The purpose of this single-blind, placebo-controlled study was to evaluate the ability of study supplement to strengthen and promote the growth of terminal hairs in adults with self-perceived thinning hair associated with poor diet, stress, hormonal influences after using it for 3 months, compared to placebo.

OBJECTIVES

The objectives of this study were:

1. Primary Objective

To evaluate the efficacy of supplement capsules compared to placebo in adults with self-perceived thinning hair

2. Secondary Objectives

To evaluate the effect of supplement capsules on the following clinical parameters in participants with self-perceived thinning hair:

- the amount of hair that fell out with each wash;
- the change in hair area compared to the starting point;
- the amount of hair in several control points compared to the starting point

METHODS

1. Overview of Study Design

Overall Design

This study was a two-arm, parallel group, double-blind, placebo-controlled trial powered to detect meaningful differences in the hair growth for people suffering from temporary thinning hair

between the treatment and control arms at 3 months. Total trial duration for participants was 3 months, and the treatment period continued for 90 days following randomization. A total of 80 males and females aged 21 to 50 with temporary thinning hair who meet all eligibility criteria were randomized in this study.

A schematic representation of the study design is presented in Schedule of Activities (SoA) scheme:

	Time of Assessment					
	Visit 1 (Screening)	*Visit 2 (Randomization)*	*Visit 3*	*Visit 4*	*Visit 5*	*Visit 6 (End of Study)*
	Day 0	*Day 1*	*Day 21*	*Day 40*	*Day 60*	*Day 90*
Eligibility	✔					
Informed Consent	✔					
Demographics	✔					
Vital Signs (HR, BP)	✔	✔	✔	✔	✔	✔
Height, weight assessment	✔					
Medical History & Current Medications	✔					
Hematology	✔					✔
Urine pregnancy test	✔					
Complete Physical Examination	✔					✔
High-quality clinical and dermoscopic photographs of hair in the target area of the scalp made by dermatoscope	✔					✔
High-quality photographs of hair in the target area of the scalp made by digital camera	✔					✔
Study Intervention randomization		✔				
Counting the amount of hair that fell out with each wash			✔	✔	✔	✔
Determining the change in hair area compared to the baseline			✔	✔	✔	✔
Counting the amount of hair in several control points compared to the			✔	✔	✔	✔

baseline						
Quality of Life Questionnaire	✔					✔
Self-assessment Questionnaire						✔

Some of the scheduled visit days were shifted for objective reasons by prior agreement with the sub-investigator.

2. Procedures performed:

Visit 1 (Screening visit)
A screening visit was carried out in order to identify eligible consenting subjects for the study. Participants were randomized on the same day as Screening. After the completion of the screening assessments, eligible participants were randomized.
The following procedures were taking place:

- Signing the informed consent document
- Demography recording
- Height, weight assessment
- Vital signs: pulse, systolic [SBP] and diastolic [DBP] blood pressure, after 10 minutes of resting position
- Medical history & Current medications
- Hematology
- A urine pregnancy test (for women of childbearing potential)
- Physical examination: general/appearance; head, eyes, ears, nose, throat, and oropharynx; skin evaluations; respiratory; cardiovascular; abdomen/gastrointestinal; urological system, musculoskeletal system and neurological system.
- High-quality clinical and dermoscopic photographs of hair in the target area of the scalp made by dermatoscope
- High-quality photographs of hair in the target area of the scalp made by digital camera
- Quality of Life Questionnaire

Visit 2 (Randomization)
Patients were considered randomized once all eligibility criteria were confirmed. Randomization visit was performed on the same day as Screening.
The following procedures were taking place:

- Vital signs: pulse, systolic [SBP] and diastolic [DBP] blood pressure, after 10 minutes of resting position
- Study Intervention randomization: participants will be assigned randomly in a 1:1 ratio to study product or placebo.

Visit 3 (Day 21), Visit 4 (Day 40), Visit 5 (Day 60)
The following procedures were taking place:

- Vital signs: pulse, systolic [SBP] and diastolic [DBP] blood pressure, after 10 minutes of resting position
- Counting the amount of hair that fell out with each wash
- Determining the change in hair area compared to the baseline
- Counting the amount of hair in several control points compared to the baseline

Visit 6 (Day 90, End of Study)
The following procedures were taking place:

- Vital signs: pulse, systolic [SBP] and diastolic [DBP] blood pressure, after 10 minutes of resting position
- Hematology
- Counting the amount of hair that fell out with each wash
- Determining the change in hair area compared to the baseline
- Counting the amount of hair in several control points compared to the baseline
- High-quality clinical and dermoscopic photographs of hair in the target area of the scalp made by dermatoscope
- High-quality photographs of hair in the target area of the scalp made by digital camera
- Quality of Life Questionnaire
- Self-assessment Questionnaire

STUDY POPULATION

1. Overview

A total of 80 males and females aged 21 to 50 with temporary thinning hair who met all eligibility criteria were randomized in this study.

2. Inclusion Criteria

Subjects had to satisfy all of the following criteria to be enrolled in the study:

1. Individuals, ages 21-50 years of age.
2. Clinically-determined general good health as determined by responses to the initial study assessment.
3. Individuals with self-perceived thinning hair associated with poor diet, stress, hormone influences.
4. Individuals willing to maintain their normal hair shampooing frequency.
5. Individuals willing to add the provided oral supplement to their current daily routine.
6. Individuals willing to not substantially change their current diet, medications, or exercise routines for the duration of the study. If a subject receives physician guidance during the study to change diet, medications, or exercise routine, the subject will need to notify the clinic as soon as possible.

7. Individuals willing to undergo a physical exam to include height, weight, blood pressure, pulse, general physical findings, scalp exam and blood sample collection.
8. Individuals with Fitzpatrick I-IV photo skin types.
9. Willingness to have digital photography of the target area and scalp for hair counts at Visits 1, 2, 3, 4, 5, 6.
10. Willingness to have their hair washed (shampooed) over a sink containing cheesecloth for hair shedding counts at Visit 1, 2, 3, 4, 5, 6.
11. Willingness to maintain a consistent haircut and hair color throughout the 3-months study period and to come to visits with clean (shampoo must be done 24 hours or more prior to the visit) and dry hair.
12. Willingness of subjects who have color treated hair to have the color treatment performed at the same time interval prior to each visit (i.e. If on Visit 1 the color treatment was done one week prior then the color treatment is expected to occur at a similar interval of one week prior to Visit 2, 3 ,4 ,5, 6).
13. Provision of signed and dated informed consent form.

3. Exclusion Criteria

Subjects were not to be enrolled into the study if they:

1. Individuals with a known history of intolerance or allergy to fish, seafood/shellfish or acerola.
2. Individuals with any known allergy or sensitivity to any shampoo/conditioner.
3. Females who are nursing, pregnant, planning to become pregnant during the study.
4. Individuals with known stressful incident within the last six months (i.e. death in family, miscarriage).
5. Individuals who are participating on any clinical research study at another research center or doctor's office.
6. Females who have recently (within the last 6 months) started the use of hormones for birth control or hormone replacement therapy (HRT). Women currently using hormones for birth control or HRT must have been on a stable dose (6 months or longer) in order to be eligible for the study.
7. Individuals currently using light therapy to treat thinning hair.
8. Individuals who have regularly used Rogaine (Minoxidil) within the last 3 months.
9. Individuals currently using any other biotin/keratin/collagen supplements.
10. Individuals who have used prescription drugs known to affect the hair growth cycle within the last 6 months (e.g., hormone-based birth control for less than 6 months, cyproterone acetate, Aldactone/spironolactone, Finasteride or any 5-alpha-reductase inhibitor).
11. Individuals suffering from other hair loss disorders, such as alopecia areata, scarring alopecia, androgenetic alopecia and telogen effluvium as determined on initial study assessment by the Investigator.

12. Individuals with self-reported uncontrolled diseases (i.e. diabetes, hypertension, hyperthyroidism, hypothyroidism, etc.). Medical conditions that are under control with or without treatment will be considered on an individual basis by the Investigators.
13. Individuals with self-reported active hepatitis, immune deficiency, HIV or autoimmune disease.
14. Individuals having a known active dermatologic condition which, in the opinion of the examining Investigators, might place the subject at a greater risk or interfere with clinical evaluations (e.g., seborrheic dermatitis, psoriasis, atopic dermatitis, advanced skin cancer, etc.).

4. Removal of Subjects from Therapy or Assessment

Administration of study product to a subject was discontinued and the subject was withdrawn from the study if any of the following occurred:

- Pregnancy.
- Significant study intervention non-compliance.
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.
- Participant unable (because of health or personal issues) to receive study intervention (study supplement or placebo).

The reason for the participant's discontinuation or withdrawal from the study should have been recorded in the subject's research documentation for that trial.
An early termination visit was conducted at the time of withdrawal from the study, according to the Assessment Schedule. The subject permanently discontinued participation in both the study drug intervention and the study at that time. Participants could withdraw from the study at any time upon request.

STUDY AGENT INFORMATION

The interventions for this study were study supplement capsules and a comparator (placebo). All investigational products were manufactured by NUTRA HARMONY LLC under the brand name “Biotin, Collagen & Keratin Beauty Complex”. Details for the study drug and placebo are shown in Table 1.

Table 1 “Details for Study Drug”

	Preparations to be Administered	
	Study Drug	**Placebo**
Study Drug Name	Biotin, Collagen & Keratin Beauty Complex	Microcrystalline cellulose (MCC)
Manufacturer	NUTRA HARMONY LLC	NUTRA HARMONY LLC
Sourcing	Provided by the sponsor	Provided by the sponsor
Packaging and Labeling	Will be provided in capsule bottle with black cap within a carton. Each carton and vial will be labeled accordingly.	Will be provided in capsule bottle with black cap within a carton. Each carton and vial will be labeled accordingly.
Formulation	Biotin, Collagen & Keratin Beauty Complex 30,000 mcg: Vitamin A 1,200 mcg RAE (4,000 IU), Vitamin D3 3 mcg (120 IU), Thiamin(vitamin B1) 5 mg, Riboflavin(vitamin B2) 5mg, Niacin(vitamin B3) 5 mg, Vitamin B6 5 mg, Folate 340 mcg DFE(200 mcg folic acid), Vitamin B12 20 mcg, Biotin 10,000 mcg, Pantothenic Acid 50 mg, Calcium 80 mg, Phosphorus 40 mg, Proprietary blend 710 mg (Fish Collagen, Methylsulfonylmethane(MSM), Hydrolyzed Keratin, Bamboo Extract (Bambusa vulgaris) (stem & leaf) (std. to 70% silica), Coconut Oil (Cocos nucifera), Nettle Extract (Urtica dioica) (root), Grape Seed Extract (Vitis vinifera)), Other ingredients: Organic Rice Flour, Cellulose (Vegetable Capsule)	Microcrystalline cellulose (MCC)
Dosage Form	Capsule	Capsule
Container/Closure	60-count capsule bottle with black cap and safety seal around the cap within a carton	60-count capsule bottle with black cap and safety seal around the cap within a carton
Route of Administration	Oral	Oral
Dose and Frequency	2 capsules daily	2 capsules daily

1. **Product packaging, storage and handling instructions**

Study product and placebo had been supplied both in similar capsule bottle with black cap within a carton. Each carton and vial had been labeled accordingly. Prepared doses of study product and placebo had been labeled by study site staff.
Study product had been stored in a secure, environmentally controlled (cool, dry place below 85°F (29°C) protected from light and heat) and monitored area with access limited to authorized site staff.

Placebo (microcrystalline cellulose) had been stored and handled at the study site under the same conditions as the study product (in a cool, dry place below 85°F (29°C), protected from light and heat).

2. Randomization and Blinding

Randomization of the intervention took place locally. There were 2 intervention groups of the study. Participants were randomly assigned 1:1 to study product or placebo.
This was a single-blind study; therefore, the Sponsor and Investigators were aware of the interventions, but the participants were blinded.

3. Dosage and Administration

At the second randomization visit, participants received one of the following 90-day doses of the study drug (until the last visit, visit 6):
• group 1: “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules
• group 2: placebo (looks like “Biotin, Collagen & Keratin Beauty Complex” 30,000 mcg, 60 capsules, but contains no active substance)

Starting from visit 2 and until visit 6, regardless of the study drug prescribed, study participants took: 1 capsule of “Biotin, Collagen & Keratin Beauty Complex” or a placebo corresponding to “Biotin, Collagen & Keratin Beauty Complex”, twice a day.

4. Treatment Compliance

When participants/caregivers performed the study intervention on site, compliance with the study intervention was assessed by on-site staff observation. The date and time of each dose administered in the clinic was recorded in the source documents. If participants/caregivers completed the study intervention at home, adherence to the study intervention was assessed at the next visit on site. A record of the number of pre-filled bottles dispensed and returned to each participant was maintained and reconciled with study intervention records and site compliance by qualified site staff.

CONCOMITANT THERAPY

For this protocol, a prescription medication was defined as a medication that can be prescribed only by a properly authorized/licensed clinician. Medications which were reported in the primary documentation are concomitant prescription medications, over-the-counter medications and supplements.

STUDY EVALUATIONS

1. Efficacy Evaluations

Descriptive statistics were obtained for all variables. Normality checks of continuous measurements were performed and data were checked for homogeneity of variance. Changes in baseline hair growth, amount of hair shedding during hair washing, quality-of-life responses, and self-report questionnaire responses were examined using repeated-measures analysis of variance. Endpoint parameters measured at each assessment were compared with baseline data using a paired t-test. Comparisons between active treatment and placebo were performed using analysis of variance (ANOVA).

- **Counting the Number of Hairs Lost During Each Wash**

The study participant washed their hair at home 24 hours before each visit to the research center. During the visit to the research center, the participant washed their hair at the center. To collect the hair lost during washing, a piece of cloth or gauze was placed over the sink. The number of hairs collected in the gauze was counted and recorded in individual forms.

- **Determination of Hair Area Change Compared to the Starting Point**

Measurements of the scalp area were taken, and phototrichograms of the selected target area were made using a dermatoscope. Using macrophotographs, the researcher determined the change in hair area in the target region of the scalp.

- **Counting the Number of Hairs at Several Control Points Compared to the Starting Number**

Phototrichograms of vellus and terminal hairs at selected target control points were performed using a dermatoscope. Macrophotographs were analyzed by a trichologist, and the number of terminal and vellus hairs at the selected target control points was determined for each participant.

- **Filling Out Questionnaires**

During the study, patients completed questionnaires at the research center. One questionnaire assessed the overall quality and how hair thinning affected their life. The other questionnaire focused on evaluating parameters related to hair, nails, and skin.

- **Comparing Effectiveness Between Groups**

When comparing effectiveness between groups, a non-parametric relationship was found, which requires consideration of dispersion for proper analysis. The aim of this study is to obtain information about the effectiveness of the "Biotin, Collagen & Keratin Beauty Complex" (60 capsules), developed by NUTRA HARMONY LLC, in promoting hair growth and reducing hair loss in individuals who believe their hair is thinning, compared to a placebo.

Efficacy assessments were performed according to the Schedule of Activities (SoA) in the protocol and described in section 1.3 of the protocol.
Data for these performance variables were recorded in the primary documentation. Some efficacy data, such as high-quality clinical and dermoscopic hair photographs, were collected and stored in electronic file format.

2. Safety Evaluations

Safety and tolerability were assessed, comparing study supplement to placebo, by clinical review of all relevant parameters including AEs, clinical laboratory test (hematology) and vital signs. The primary approach to analysis of safety were including all data through 90 days on treatment. AEs were coded using the standard MedDRA.

Descriptive statistics for vital signs were presented by randomization group and time point assessed. Descriptive statistics for the change from baseline to each post-baseline time point for the vital sign parameters were summarized by randomization group.

With the exception of clinical laboratory data, the data for these safety variables were recorded in the primary documentation. All clinical laboratory tests were analyzed by a local laboratory and a study site personnel. The clinical laboratory data were collected and recorded in the primary documentation. The timing of all safety procedures was described in the the Schedule of Activities (SoA) in the protocol which located in section 1.3 of the protocol.

3. Adverse Events

Adverse events were either reported by the subject voluntarily or were obtained by means of interviewing subjects in a nondirected manner at study visits. Adverse event definitions, attributions, and severity criteria are listed in the protocol.

All AEs were described and recorded on the subject's source document including date of onset, seriousness, severity, outcome and action taken, and relationship as evaluated by the investigator. In the event of a serious adverse event (SAE) or unexpected AE, the study sponsor was notified as specified in the protocol.

Adverse events of interest were: hematologic laboratory abnormalities, hypersensitivity reactions.

4. Pregnancy

No pregnancies were reported during the study.

5. Adverse Events Resulting in Removal of Subjects from Therapy or Assessment

Adverse events were reported for one subject from group 1: study supplement and one subject from group 2: placebo. Both subjects discontinued study assessment.

6. Serious Adverse Events

No SAE were reported during the study.

QUALITY CONTROL AND DATA QUALITY ASSURANCE

The Investigator had the education, professional training and experience that allowed to take responsibility for the proper conduct of the clinical trial. The qualification of the Investigator met the regulatory requirements and was confirmed by his scientific biography (curriculum vitae) and other documents that were provided to the Sponsor before the start of the study.
The Primary Investigator kept a list of persons with the necessary qualifications who, on his behalf, carried out certain activities within the framework of the study.

STUDY DOCUMENTATION

Before the start of the study, the investigator provided the Sponsor with the following documents:

- Signed contract between the research center and the Sponsor for conducting the clinical study;
- License of the healthcare facility for medical practice;
- Accreditation certificate of the healthcare facility;
- List of research team members with assigned responsibilities;
- Scientific biographies (CVs) of all research team members;
- Certificates of investigators for completing GCP training (if available);
- Order for the establishment of the Ethics Committee at the healthcare facility;
- Composition of the Ethics Committee at the healthcare facility;
- Document from the Ethics Committee at the healthcare facility approving the protocol and other materials of the clinical trial;
- Normal values/normal ranges for clinical/laboratory/instrumental tests/researches provided in the clinical trial protocol;
- Documents confirming certification or accreditation, or internal and/or external quality control of laboratory equipment, and other verification methods.

Before the start of the study, the Sponsor provided the research center with the following documents:

- Act of transfer of the investigational products;
- Current version of the clinical study protocol;
- Individual patient registration forms (in the required quantity);
- Informed consent forms and patient information forms (in the required quantity);
- Instructions for the medical use of the drug;
- Copy of the insurance certificate;
- Certificate of quality of the investigational/reference drug;

CLINICAL STUDY MONITORING

The monitoring of the clinical study was conducted by the Sponsor. Monitoring of the research center was carried out through site visits, telephone contacts, and regular review of CRFs at a frequency sufficient to assess patient recruitment rates, adherence to the study protocol, completeness and accuracy of the data entered into the CRFs, and the occurrence of Adverse Events (AEs) / Adverse Reactions (ARs).

The investigator provided the Sponsor representatives with the opportunity to:

- Visit the research center, access the area where the study is conducted, and review study materials;
- Meet with members of the research team and access the study documentation;
- Verify the accuracy of CRF completion and reconcile CRFs with primary medical documentation;

All information related to study monitoring is considered strictly confidential.

STATISTICAL METHODS PLANNED IN THE CLINICAL STUDY PROTOCOL

1. **Justification of Sample Size**

The sample size is assessed based on the primary variable of the trial and depends on its type. This trial is a simple, blind, randomized, placebo-controlled study.

Primary variables include the increase in hair growth in subjects who received the study supplement, noted by determining the change in hair area compared to the baseline and counting the number of hairs at several control points compared to patients who received a placebo after 90 days of supplement intake.

2. **Secondary Endpoints of the Study**

Secondary endpoints were determined using microscopic photographs to measure the hair growth area after washing to count the number of hairs lost in subjects who received the study supplement compared to those who received a placebo, and changes in patient self-assessment based on

questionnaires after treatment.

3. Subject and information

3.1 Subject Disposition and Study Completion/Withdrawal Information

In this study 80 subjects were enrolled. Consent was obtained from the first subject on 19 February 2024. The last study-related procedure was performed on 12 July 2024.

3.2 Discontinuation of Study Agent and Termination of Study Participation

Of the 80 subjects who entered the study, 2 subjects discontinued study supplement/placebo due to an AE and one subject discontinued study agent due to loss of follow-up. Seventy-seven subjects completed the final visit.

3.3 Distribution of Subjects

Normally, approximately 90% of all hair is in the anagen phase (growth), 3% (rest) is in the catagen phase, and 7% (stop and shedding) is in the telogen phase. According to the protocol requirements, patients were included in comparative groups based on age: 21-30 years, 31-40 years, and 41-50 years, both in the placebo group and in the dietary supplement group. The symptoms presented by patients were predominantly categorized into the following groups: thinning, weakening, inflammatory processes in the scalp and blood vessels, skin flaking, increased oiliness, and an increase in the amount of vellus hair compared to mature hair. Only a small percentage of volunteers who took the placebo did not exhibit these processes and could be considered conditionally healthy. The data are presented in Table 2 for women and Table 3 for men.

Table 2. Distribution of participants by the nature of scalp and hair symptoms in women at baseline

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair shedding (1-2 hairs per unit)	5	9	10	5	7	6
Hair thinning	2	7	6	6	4	5
Inflammatory processes in the scalp and blood vessels	3	7	4	6	4	6
Increased distance between units	2	3	7	2	2	4
Increase in the amount of vellus hair compared to mature hairs	2	3	5	3	5	0

Table 3. Distribution of participants by the nature of scalp and hair symptoms in men at baseline

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair shedding (1-2 hairs per unit)	2	1	0	4	1	1
Hair thinning	2	1	0	5	0	0
Inflammatory processes in the scalp and blood vessels	1	0	0	5	1	1
Increased distance between units	1	1	0	3	1	1
Increase in the amount of vellus hair compared to mature hairs	1	0	0	1	1	0

After analysis, we understand that the differences in the frequency of symptom occurrence between women and men are statistically insignificant.

Table 4. Distribution of participants by the nature of scalp and hair symptoms in women one month after starting treatment

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years

Hair shedding (1-2 hairs per unit)	4	8	8	5	7	6
Hair thinning	2	6	6	6	4	5
Inflammatory processes in the scalp and blood vessels	3	6	4	5	4	6
Increased distance between units	2	3	6	2	2	4
Increase in the amount of vellus hair compared to mature hairs	3	4	6	3	5	0

Table 5. Distribution of participants by the nature of scalp and hair symptoms in women three months after starting treatment

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair shedding (1-2 hairs per unit)	2	4	3	4	6	6
Hair thinning	1	3	2	5	4	4
Inflammatory processes in the scalp and blood vessels	1	2	3	5	3	6
Increased distance between units	1	1	2	1	2	4
Increase in the amount of vellus hair compared to mature hairs	6	7	8	3	5	1

Table 6. Distribution of participants by the nature of scalp and hair symptoms in men three months after starting treatment

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair shedding (1-2 hairs per unit)	1	0	0	3	1	1
Hair thinning	0	1	0	4	0	0
Inflammatory processes in the scalp and blood vessels	0	0	0	4	1	1
Increased distance between units	0	1	0	3	1	1

Increase in the amount of vellus hair compared to mature hairs	2	1	0	1	1	0

Table 7. Distribution of participants in percentage terms by the nature of hair problem manifestations at baseline relative to the total number of individuals in each study group (women)

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years, %	31-40 years, %	41-50 years, %	21-30 years, %	31-40 years, %	41-50 years, %
Hair shedding (1-2 hairs per unit)	71,43	60,00	67,78	62,50	77,78	46,15
Hair thinning	28,57	46,67	40,00	75,00	44,44	38,46
Inflammatory processes in the scalp and blood vessels	42,86	46,67	26,67	75,00	44,44	46,15
Increased distance between units	28,57	20,00	46,67	25,00	22,22	30,78
Increase in the amount of vellus hair compared to mature hairs	28,57	20,00	33,33	37,50	55,56	0

Table 8. Distribution of participants in percentage terms by the nature of hair problem manifestations at one month of the study relative to the total number of individuals in each study group (women)

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years, %	31-40 years, %	41-50 years, %	21-30 years, %	31-40 years, %	41-50 years, %
Hair shedding (1-2 hairs per unit)	57,14	53,33	53,33	62,50	77,78	46,15
Hair thinning	28,57	40,00	40,00	75,00	44,44	38,46
Inflammatory processes in the scalp and blood vessels	42,86	40,00	26,67	62,50	44,44	46,15
Increased distance between units	28,57	20,00	40,00	25,00	22,22	30,78
Increase in the amount of vellus hair compared to mature hairs	42,85	26,67	40,00	37,50	55,56	0

Table 9. Distribution of participants in percentage terms by the nature of hair problem manifestations at three months of the study relative to the total number of individuals in each study group (women)

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years, %	31-40 years, %	41-50 years, %	21-30 years, %	31-40 years, %	41-50 years, %
Hair shedding (1-2 hairs per unit)	28,57	26,67	20,00	50,00	66,67	46,15
Hair thinning	14,29	20,00	13,33	62,50	44,44	30,77
Inflammatory processes in the scalp and blood vessels	14,29	13,33	20,00	62,50	33,33	46,15
Increased distance between units	14,29	6,67	13,33	12,50	22,22	30,78
Increase in the amount of vellus hair compared to mature hairs	85,71	46,67	53,33	37,50	55,56	7,69

Compared to baseline, the hair area increased due to the activation of the anagen phase and the extension of the catagen phase.

As seen from the tables, the amount of vellus (young) hair in women increased 3.64 times in the age group of 20 to 30 years, 2.33 times in the age group of 31 to 40 years, and 1.6 times in the age group of 41 to 50 years after three months of taking the dietary supplement, compared to baseline.

In contrast, for the placebo group, changes were as follows: no changes were observed in the 20-30-year age group, no changes were noted in the 31-40-year age group, and in the 41-50-year age group, changes in the amount of hair in the anagen phase were noted in a few women, who also reported improvements in digestive processes, which could be a reason for these changes.

Analyzing hair thinning in the groups of volunteers who took the dietary supplement, the situation improved twofold for women in the 20-30-year age group, based on the number of participants who reported hair thinning at the three-month mark compared to baseline.

In the 31-40-year age group, the situation improved 2.33 times, and in the 41-50-year age group, the situation improved threefold compared to baseline.

For the placebo group, the situation in the youngest group improved by 20%, in the 31-40-year group the situation did not change after three months, and in the older age group, the situation improved by 33.7%, which is most likely related to the normalization of digestive processes for these participants.

Table 10. Distribution of participants in percentage terms by the nature of hair problem manifestations at baseline relative to the total number of individuals in each study group (men)

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years, %	31-40 years, %	41-50 years, %	21-30 years, %	31-40 years, %	41-50 years, %
Hair shedding (1-2 hairs per unit)	100,00%	100,00 %	0	80,00%	100,00%	100,00 %
Hair thinning	100,00%	100,00 %	0	100,00%	0	100,00 %
Inflammatory processes in the scalp and blood vessels	50,00%	0	0	100,00%	100,00%	100,00 %
Increased distance between units	50,00%	100%	0	60,00%	100,00%	100,00 %
Increase in the amount of vellus hair compared to mature hairs	50,00%	0	0	20,00%	100,00%	0

Table 11. Distribution of participants in percentage terms by the nature of hair problem manifestations at three months of the study relative to the total number of individuals in each study group (men)

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years, %	31-40 years, %	41-50 years, %	21-30 years, %	31-40 years, %	41-50 years, %
Hair shedding (1-2 hairs per unit)	50,00%	0	0	60,00%	100,00%	100,00 %
Hair thinning	0	100,00 %	0	80,00%	0	100,00 %
Inflammatory processes in the scalp and blood vessels	0	0	0	80,00%	0	100,00 %
Increased distance between units	0	0	0	100,00%	100,00%	100,00 %
Increase in the amount of vellus hair compared to mature hairs	200,00%	100%	0	0	0	0

Compared to baseline, the hair area increased due to the activation of the anagen phase and the extension of the catagen phase.

As seen from the tables, the amount of vellus (young) hair in men increased fourfold in the age group of 20 to 30 years and twofold in the age group of 31 to 40 years after three months of taking the dietary supplement, compared to baseline. There was no group for men aged 41 to 50.

In the placebo group, there was no increase in hair area for men; that is, the hair growth area did not change, and the number of hairs per measurement point also remained at baseline levels.

4. **Null and Alternative Hypotheses**

For this trial, where the primary variable is dichotomous, let P_{SUP} and P_{PL} represent the proportion of "positive results" (category: "no improvement in hair condition and no change in hair area at 90 days after the start of treatment") when comparing different age groups and genders between the dietary supplement and the corresponding placebo groups. The null hypothesis is formulated as follows:

$H_0: | P_{SUP} - P_{PL} | \geq \delta,$

and the alternative hypothesis, H_a, will be:

$H_a: | P_{SUP} - P_{PL} | < \delta,$

where δ represents the magnitude of clinically significant differences.

Since evaluating the sample size should also consider that conclusions about the pharmaceutical effectiveness of the dietary supplement compared to the placebo (as an ineffective clinical product) should be based on a confidence interval approach.

Based on the above, the size of the primary group, assuming patients are distributed into groups in a 1:1 ratio, can be estimated using the following statement:

$$n = \frac{2p(100 - p)(z_{1-\alpha/2} + z_{1-\beta/2})^2}{\delta^2}$$

where

- p is the size of the positive effect of the dietary supplement (in our case, P_{SUP}), estimated from previous studies (measured as a percentage), assuming that the effect size of the investigated product will be the same;

- a is the maximum probability of making a Type I error (significance level or the probability of

accepting the null hypothesis);

- b is the maximum probability of making a Type II error;

- $z_{1-\alpha/2}$ and $z_{1-\beta/2}$ are the corresponding upper percentiles of the standard normal distribution;

- d is the maximum acceptable magnitude of clinically significant differences, where the investigated product is considered equivalent to the comparison product if the differences in effectiveness between the compared products do not exceed this value.

Based on standard practice and regulatory requirements [2, 3], the following parameter values are typically used for such trials: a = 0,05 (two-tailed); b = 0,2 (which provides 80% statistical power). According to literature, experience, and results from previous clinical studies of dimethindene products, the maximum positive effect size of the reference product is on average 95%.

The magnitude of clinically significant differences d, according to [2], should be determined based on clinical judgment and be statistically justified. Since d essentially represents that the difference in the magnitude of the positive effect (in this case, the difference in proportions) along with confidence intervals should fall within the therapeutic equivalence range (from $–d$ to $+d$), for this study, the magnitude of clinically significant differences was taken as 16% (d=16%).

Substituting the initial data into the above formula for sample size estimation, the calculated number of patients in each group should be:

$$n = \frac{2 \cdot 95 \cdot (100 - 95) \cdot (1{,}96 + 1{,}24)^2}{16^2} = 38.$$

Based on prior experience and results from earlier studies of generic versions of this product, it is known that up to 5% of patients may drop out from such a trial. Therefore, to ensure the required 80% power of the study, each group needs to be increased by 5%, which raises the number of patients in each group to 40.

5. **Analysis of Baseline Homogeneity of Groups**

Conduct an analysis of group homogeneity based on clinical-demographic indicators and efficacy indicators. To do this:

a) Use descriptive statistics to describe the baseline state of the primary and control groups. For quantitative indicators, report: sample size (n), mean, median, standard deviation, minimum and maximum values; for qualitative indicators, report: frequency and percentage.

b) For quantitative indicators, check the normality of data distribution in the groups using the

Shapiro-Wilk test. If the data in the groups for specific indicators are normally distributed, compare the groups using the Student's t-test for independent samples (after checking the homogeneity of variances in the groups using Levene's test to choose the appropriate version of the Student's t-test). Otherwise (if data are not normally distributed), perform group comparisons using the Mann-Whitney U test.

c) To make statistical conclusions about the baseline homogeneity of the groups based on the specified variables

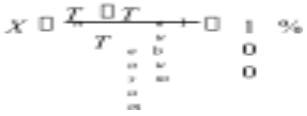
6. **Analysis of Effectiveness in Each Group**

Determine the effectiveness of the therapy in the dietary supplement group compared to the placebo group using the following variables:

- Data on the number of hairs lost at each stage in each group
- Data on hair condition and control points
- Data on patient-reported subjective complaints at the start and end of the study
- Overall comparative effectiveness of the placebo and dietary supplement

a) **Clinical Indicators Expressed on a Rating Scale:**

- Report descriptive statistics for visits T1, T3, and T4 in each group (n, mean, median, standard deviation, minimum, and maximum values).
- Calculate the relative change for each indicator in each group at subsequent visits compared to the baseline using the formula:



Where n – visit 3, visit 4.

Assess the trend of changes in the mean values of these indicators graphically by constructing the relevant graphs.

- To evaluate the dynamics of this parameter in the groups, perform a two-way ANOVA in each group based on a mixed model (dependent variable — parameter; factors: "time" — fixed (levels: T1, T3, T4) and "patients" — random).

b) **Categorical Indicators:**

- Report descriptive statistics for categorical indicators at T1, T3, and T4 in each group (frequency and percentage).
- Present their graphical dynamics.

7. **Comparing Therapy Effectiveness Between Groups**

a) **Comparing Effectiveness in Groups:**

- Compare the effectiveness between groups for the studied indicators by calculating dT1=(Visit 3−Visit 1) and dT4=(Visit 4−Visit 1)
- If the groups are statistically non-significant at the first visit for a specific indicator, test the normality of the distribution of dT3 and dT4 in each group using the Shapiro-Wilk test. Compare the groups for these parameters using the Student's t-test for independent samples or the Mann-Whitney U test, depending on the results of the normality test.
- If the groups are statistically significant at the first visit for a specific indicator, perform a covariance analysis for dT of the given indicator using the following model:
    - Dependent variable: the analyzed indicator
    - Factor "group" - fixed (levels: primary, control)
    - Covariate - value of the indicator at the first visit.
- Check the normality of the residuals from the covariance analysis using the Shapiro-Wilk test. If the residuals are not normally distributed, perform a rank-based analysis.

8. **Significance Levels**

- The significance level for the Shapiro-Wilk test should be set at 0.01, while for other tests, it should be set at 0.05.

9. **Conclusion on Therapeutic Action**

- The conclusion regarding the equivalence of the two studied products, the dietary supplement and placebo, based on efficacy indicators, will use a confidence interval approach. To do this:
    - Calculate the 95% confidence interval boundaries for the difference in proportions of positive results between the experimental and control groups.
    - Compare these boundaries with the equivalence zone limits (16%; ±16%).
    - If the lower limit of the confidence interval is greater than the lower limit of the equivalence zone and the upper limit of the confidence interval is less than the upper limit of the equivalence zone, then the investigated product will be considered equivalent to the comparison product in terms of efficacy.

10. **Patients Included in the Analysis**

- The effectiveness analysis will include patients who completed a 90-day course of the dietary supplement or placebo. Volunteers who have violated the requirements of this protocol (inclusion/exclusion criteria, treatment regimen, prescription of non-recommended concomitant therapy, etc.), as well as patients who dropped out of the study due to adverse reactions, will not be included in the effectiveness analysis.

11. **Changes in the Conduct of the Planned Study or in the Planned Analysis**

- No changes have been made to the study plan or data analysis.

Table 12: Distribution of Volunteers by Gender

Gender	Dietary Supplement		Placebo		Total	
	n	%	n	%	N	%
Men	3	7,5	7	18,9	10	12,98
Women	37	92,5	30	81,08	67	87,01
Total	40	100	37	100	77	100

To assess the homogeneity of groups by gender, the Pearson chi-square test with continuity correction is typically used. In our case, the analysis indicates that gender does not have a significant impact on the results. Therefore, despite the non-homogeneous distribution by gender, it can be concluded that, according to the results from the use of the supplement and placebo, there are no significant differences in the effects on hair growth, its condition, or thinning based on gender.

Table 13: Distribution of Volunteers by Age in the Dietary Supplement Group

Gender	21-30 years		31-40 years		41-50 years	
	n	%	N	%	n	%
Men	2	22,2	1	6,25	0	0
Women	7	77,8	15	93,75	15	100
Total	9	100	16	100	15	100

Table 14: Distribution of Volunteers by Age in the Placebo Group

Gender	21-30 years	31-40 years	41-50 years

	n	%	N	%	n	%
Men	5	38,46	1	10	1	7,14
Women	8	61,54	9	90	13	92,86
Total	13	100	10	100	14	100

12. **Medical History Data**

Trichoscopic examination was conducted using the Aramo-SG trichoscope (AramoSG® Skin & Hair Diagnosis System, Korea) with subsequent image analysis (macro-, ×20-, ×60-fold magnification) and assessment of the primary trichoscopic criteria for hair disorders.

Normally, approximately 90% of all hair is in the anagen phase (growth), 3% (rest) is in the catagen phase, and 7% (cessation and shedding) is in the telogen phase.

According to the protocol requirements, patients were included in the study in comparative groups of 21-30 years, 31-40 years, and 41-50 years for both the placebo group and the dietary supplement group. Symptoms predominantly observed in patients were grouped as follows: thinning, reduction in hair thickness, inflammatory processes in the scalp and blood vessels, scaling of the skin, increased oiliness, and an increase in the number of vellus hairs compared to terminal hairs. Only a small percentage of volunteers receiving placebo did not exhibit these processes and could be considered conditionally healthy. Data are presented in Table 15 for women and Table 16 for men.

Table 15: Distribution of Female Participants by Type of Scalp and Hair Symptomatology

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair thinning (1-2 hairs per unit) or increasing the distance between units	3	8	6	6	7	9
Hair thinning	4	7	3	6	4	11
Inflammatory processes in the scalp and blood vessels	3	7	4	6	4	6
Skin peeling	1	3	6	2	5	6
Disruption of	1	0	0	2	0	1

sebum regulation						
Increased number of vellus hairs compared to terminal hairs or one hair per unit	2	3	5	3	5	0

Table 16: Distribution of Male Participants by Type of Scalp and Hair Symptomatology

Symptoms of the disease	Dietary supplement			Placebo		
	21-30 years	31-40 years	41-50 years	21-30 years	31-40 years	41-50 years
Hair thinning (1-2 hairs per unit) or increasing the distance between units	1	1	0	4	1	1
Hair thinning	0	1	0	5	0	0
Inflammatory processes in the scalp and blood vessels	1	0	0	0	1	0
Skin peeling	1	1	0	0	0	0
Disruption of sebum regulation	0	1	0	1	1	0
Increased number of vellus hairs compared to terminal hairs or one hair per unit	0	0	0	0	1	0

After analysis, we understand that the differences in the frequency of symptom occurrence between women and men are statistically insignificant.

Upon analyzing the tabular data, it becomes clear that:

A. For women of all age groups, the intake of dietary supplements led to an overall improvement:

In the group of women aged 21 to 30:

1. Women aged 21 to 30 saw an improvement after one month of taking the supplement, with hair loss reduced by 32.35%.
2. Women aged 21 to 30 saw an improvement after two months of taking the supplement, with hair loss reduced by 4.35% compared to the first month, and a total reduction of 32.29% compared to baseline.
3. Women aged 21 to 30 saw an improvement after three months of taking the supplement, with hair loss reduced by 54.55% compared to the second month, and a total reduction of 70.59% compared to baseline.

In the group of women aged 31 to 40:

1. Women aged 31 to 40 saw an improvement after one month of taking the supplement, with hair loss reduced by 20%.
2. Women aged 31 to 40 saw an improvement after two months of taking the supplement, with hair loss reduced by 20.83% compared to the first month, and a total reduction of 36.67% compared to baseline.
3. Women aged 31 to 40 saw an improvement after three months of taking the supplement, with hair loss reduced by 47.37% compared to the second month, and a total reduction of 66.67% compared to baseline.

In the group of women aged 41 to 50:

1. Women aged 41 to 50 saw an improvement after one month of taking the supplement, with hair loss reduced by 31.43%.
2. Women aged 41 to 50 saw an improvement after two months of taking the supplement, with hair loss reduced by 12.5% compared to the first month, and a total reduction of 40% compared to baseline.
3. Women aged 41 to 50 saw an improvement after three months of taking the supplement, with hair loss reduced by 33.33% compared to the second month, and a total reduction of 60% compared to baseline.

B. For women of all age groups, the intake of placebo led to the following overall situation:

In the group of women aged 21 to 30:

1. Women aged 21 to 30 saw an improvement after one month of taking the placebo, with hair loss reduced by 28%.

2. Women aged 21 to 30 had no change after two months of taking the placebo, with hair loss remaining the same on average (0% change) compared to the first month, and a total reduction of 28% compared to baseline. No progress was observed between the first and second months.
3. Women aged 21 to 30 saw an improvement after three months of taking the placebo, with hair loss reduced by 16.67% compared to the second month, and a total reduction of 40% compared to baseline.

In the group of women aged 31 to 40:

1. Women aged 31 to 40 saw an improvement after one month of taking the placebo, with hair loss reduced by 7.5%.
2. Women aged 31 to 40 saw an improvement after two months of taking the placebo, with hair loss reduced by 2.7% compared to the first month, and a total reduction of 10% compared to baseline.
3. Women aged 31 to 40 saw an improvement after three months of taking the placebo, with hair loss reduced by 19.4% compared to the second month, and a total reduction of 26.47% compared to baseline.

In the group of women aged 41 to 50:

1. Women aged 41 to 50 saw an improvement after one month of taking the placebo, with hair loss reduced by 23.53%.
2. Women aged 41 to 50 had no change after two months of taking the placebo, with hair loss remaining the same compared to the first month, and a total reduction of 23.53% compared to baseline.
3. Women aged 41 to 50 saw an improvement after three months of taking the placebo, with hair loss reduced by 3.85% compared to the second month, and a total reduction of 26.47% compared to baseline.

C. For women of all age groups, the intake of dietary supplements compared to placebo affected the change in hair loss as follows:

In the group of women aged 21 to 30:

1. After one month of taking the supplement, women aged 21 to 30 saw an improvement, with hair loss reduced by 32.35% compared to a 28% reduction with placebo.
2. After two months of taking the supplement, women aged 21 to 30 saw an improvement, with hair loss reduced by 4.35% compared to a 0% change with placebo, and a total reduction of 32.29% compared to baseline with the supplement versus 28% with placebo.
3. After three months of taking the supplement, women aged 21 to 30 saw an improvement, with hair loss reduced by 54.55% compared to a 16.67% reduction with placebo, and a total reduction of 70.59% compared to baseline with the supplement versus 40% with placebo.

In the group of women aged 21 to 30, during the three months of taking the supplements, statistically significant improvement was observed, specifically:

1. At the end of the first month, the difference between the dietary supplement and placebo was 13.45%.
2. At the end of the second month, the difference between the dietary supplement and placebo was 43.5%, as no changes were observed with placebo on average. Compared to baseline, the reduction was 26.9%.
3. At the end of the third month, the difference between the dietary supplement and placebo was 69.44%. Compared to baseline, the reduction was 43.33%.

In the group of women aged 31 to 40:

1. After one month of taking the supplement, women aged 31 to 40 saw an improvement, with hair loss reduced by 20% compared to a 7.5% reduction with placebo.
2. After two months of taking the supplement, women aged 31 to 40 saw an improvement, with hair loss reduced by 20.83% compared to a 2.7% reduction with placebo from the first month. The total reduction compared to baseline was 36.67% with the supplement versus 10% with placebo.
3. After three months of taking the supplement, women aged 31 to 40 saw an improvement, with hair loss reduced by 47.37% compared to a 19.4% reduction with placebo from the second month. The total reduction compared to baseline was 66.67% with the supplement versus 26.47% with placebo.

In the group of women aged 31 to 40, statistically significant improvement was observed over the three months of taking the supplements, specifically:

1. At the end of the first month, the difference between the dietary supplement and placebo was 62.5%.
2. At the end of the second month, the difference between the dietary supplement and placebo was 87%, as no average change was observed with placebo. Compared to baseline, the reduction was 72.73% with the supplement.
3. At the end of the third month, the difference between the dietary supplement and placebo was 59%. Compared to baseline, the reduction was 60.3% with the supplement.

In the group of women aged 41 to 50:

1. After one month of taking the supplement, women aged 41 to 50 saw an improvement, with hair loss reduced by 31.43% compared to a 23.53% reduction with placebo.
2. After two months of taking the supplement, women aged 41 to 50 saw an improvement, with hair loss reduced by 12.5%, while no change was observed in the placebo group compared to the first month. The total reduction compared to baseline was 40% with the supplement versus 23.52% with placebo.

3. After three months of taking the supplement, women aged 41 to 50 saw an improvement, with hair loss reduced by 33.33% compared to a 3.85% reduction with placebo from the second month. The total reduction compared to baseline was 60% with the supplement versus 26.47% with placebo.

In the group of women aged 41 to 50, statistically significant improvement was observed over the three months of taking the supplements, specifically:

1. At the end of the first month, the difference between the dietary supplement and placebo was 25.13%.
2. At the end of the second month, the difference between the dietary supplement and placebo was 125%, as no average change was observed with placebo. Compared to baseline, the reduction was 41.2% with the supplement.
3. At the end of the third month, the difference between the dietary supplement and placebo was 88.45%. Compared to baseline, the reduction was 55.88% with the supplement.

Arithmetic mean values of variables for the active ingredient supplement among 41 volunteers according to randomization, with 1 screener excluded.									
Gender	Total number	Age	Amount	1	2	1	2	3	4
				Average questionnaire score at the visit 1	Average questionnaire score at the final visit	Amount of hair lost during each wash (at baseline)	Amount of hair lost during each wash (after 1 month)	Amount of hair lost during each wash (after 2 months)	Amount of hair lost during each wash (after 3 months)
F	37	21-30	7	23	8	34	23	22	10
		31-40	15	21	5	30	24	19	10
		41-50	15	24	9	35	24	21	14
M	3	21-30	2	5	0	18	13		12
		31-40	1	11	6	30	25	20	15
		41-50	0	0	0	0	0	0	0
Arithmetic mean values of variables for placebo among 42 volunteers according to randomization, with 5 screeners excluded									
Gender	Total number	Age	Amount	1	2	1	2	3	4
				Average questionnaire score at the visit 1	Average questionnaire score at the final visit	Amount of hair lost during each wash (at baseline)	Amount of hair lost during each wash (after 1 month)	Amount of hair lost during each wash (after 2 months)	Amount of hair lost during each wash (after 3 months)
F	30	21-30	8	29	5	50	36	36	30
		31-40	9	23	39	40	37	36	29
		41-50	13	19	34	34	26	26	25
M	7	21-30	5	16	6	19	21	21	15
		31-4	1	1	0	10	20	10	16

		0							
		41-50	1	11	10	15	30	30	35

For men of all age groups, the intake of dietary supplements led to an overall improvement compared to placebo, starting from the second month of treatment.

Calculations will be included in the report, as the trend across age groups remains consistent.

CONCLUSIONS

1. The supplement “Biotin, Collagen & Keratin Beauty Complex” manufactured by NUTRA HARMONY LLC is an effective supplement for individuals with self-perceived thinning hair. The action of the supplement involves reducing the severity of the clinical manifestations of hair-loss and the intensity of subjective complaints from the study participants.

2. According to the study results, the course of the dietary supplement “Biotin, Collagen & Keratin Beauty Complex” manufactured by NUTRA HARMONY LLC was found to be effective compared to placebo after comparison in two separate groups.

3. Based on the data from the conducted study, the hypothesis is confirmed that taking the "Beauty Complex with Biotin, Collagen, and Keratin" manufactured by NUTRA HARMONY LLC for more than three months strengthens and stimulates the growth of terminal hair in individuals aged 21-50 with hair thinning related to poor nutrition, stress, and hormonal influences, compared to taking a placebo.

4. The supplement “Biotin, Collagen & Keratin Beauty Complex” manufactured by NUTRA HARMONY LLC was well tolerated by subjects, did not cause serious adverse reactions, negative changes in objective examination data, or laboratory indicators.

5. The supplement “Biotin, Collagen & Keratin Beauty Complex” manufactured by NUTRA HARMONY LLC is an effective and safe dietary supplement and can be recommended as a supplement for promotion of hair thickness and hair strength in individuals with self-perceived thinning hair.

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