

Adipose-derived Stromal Vascular Fraction Injections to Stimulate Hair Regrowth for Androgenetic Alopecia

PROTOCOL: GIDAA-01 Rev: D

Study Sponsor: The GID Group, Inc.
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Sponsor Contact Director of Clinical Affairs

Date: March 24, 2016

The study will be conducted in accordance with the design and specific provisions of this IRB approved protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirement(s). The Principal Investigator will assure that no deviation from, or changes to; the protocol will take place without prior agreement from the sponsor and documented approval from the IRB, except where necessary to eliminate an immediate hazard(s) to the trial participants. The Principal Investigator will promptly report to the IRB and the sponsor any changes in research activity and all unanticipated problems involving risk to human subjects, or others.

I have read and agree to follow the procedures as outlined in this protocol.

Signature of Investigator

Date

SUMMARY

Objectives:

The general objective of this study is to conduct a safety and feasibility study of a single injection of autologous adipose-derived SVF for the treatment of alopecia.

Specific Objectives

1. Safety - Adverse Events
2. Feasibility – Pre-op to post-op hair density (number of hairs per square centimeter) and hair thickness

Design:

This is a prospective, non-randomized, non-blinded, interventional, consecutive series, multiple site study to determine initial safety and feasibility of a single injection of autologous adipose-derived SVF for the treatment of alopecia.

Subject Population:
Inclusion Criteria:

1. Males and females 18 - 60 years of age that have been diagnosed with androgenetic alopecia.
2. Subjects will be in good health (ASA Class I-II) with a BMI < 35.
3. Must have at least a 2cm x 2cm spot on the scalp which shows evidence of alopecia without scarring or traumatic injury
4. Able and willing to make the required study visits.
5. Able and willing to give consent and follow study instructions.
6. Must speak, read and understand English

Exclusion Criteria:

1. History of bleeding disorders, anticoagulation therapy that cannot be stopped 14 days prior to injection
2. Allergic to lidocaine, epinephrine, valium or sodium phosphate
3. Individuals with a propensity for keloids
4. Individuals with diminished decision-making capacity will not be included in this research study.
5. Current use of anti-inflammatory or anticoagulation medications that affect bleeding or are for bleeding disorders. These include: Plavix, Warfarin (Coumadin, Jantoven, Marfarin).
6. Use of concomitant treatments, including topical medications, oral medications, meso-therapy, non-ablative fractional laser treatment, low-level laser therapy, interfollicular PRP injection and hair transplantation within the preceding 6 months.
7. All smokers and other tobacco users.

Subject Recruitment Methods:	Subjects will be recruited from the practice of the Principal Investigator (PI) at each site and/or other colleagues and healthcare professionals in the community. Recruitment will be prospective for this study. Subjects will be recruited via; 1) email utilizing a list of patients that have given their prior consent to be contacted in this manner 2) at the PI's office when they come in for their regularly scheduled appointments or 3) referrals from healthcare professionals within the community or 4) via IRB approved flyers.
Investigational Sites	Up to 3 sites
Estimated Total Sample Size	Eight (8) subjects will be recruited to participate in the study. This study is a small pilot safety and feasibility study not requiring sample size.
Plan for Data Analysis:	Adverse events will be recorded. Hair density (hairs per square centimeter) and hair thickness will be compared pre and post treatment.

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1 Introduction

Androgenetic alopecia (AGA) is the most common form of hair loss and affects 50% and 23% of Caucasian men and women, respectively, over the age of 50. The percentage of men and women affected over the age of 70 increases to 80% and 60% of Caucasian men and women, respectively^{1,2}. Although alopecia is considered a minor dermatologic condition, it is seen as a serious condition with major life consequences by those with alopecia and has been associated with increased incidence of myocardial infarction, hypertension and hypercholesterolaemia^{3,4}. Androgenetic alopecia is associated with feelings of anxiety, depression and various personality disorders among men and women due to physical appearance³⁻⁶. Depression, anxiety, aggressiveness, impaired quality of life and social inadequacy have been documented. The presence of alopecia in women is particularly stressful^{5,7}.

Human Clinical Studies

Two studies have recently been published that used adipose-derived SVF cells for hair regrowth in humans and have found it to be safe and effective. Shin et al retrospectively examined 27 women who received 12 injections (one injection per week) of adipose-derived SVF for treatment of alopecia⁸. After 12 weeks hair density and thickness significantly increased with no adverse events reported.

Fukuoka et al reported on 2 groups of patients with alopecia⁹. One group had 11 men and 11 women that were treated with 6 injections spaced every 3 to 5 weeks of adipose-derived SVF and monitored for up to 7 months. They found a significant increase in hair growth and reported no adverse events or safety issues. In the second group 10 patients (8 men and 2 women) were treated on one side with adipose-derived SVF and the other with placebo (saline). Patients were blinded to the treatment. This group also received 6 injections similar to the other group. The treatment group had significantly more hair growth than the control side.

A hair regeneration procedure that is less invasive than surgical hair transplantation, entails less risk than current surgical treatments, and is less time consuming would benefit men and women with alopecia.

2 Study Objectives

The general objective of this study is to conduct a safety and feasibility study of a single injection of autologous adipose-derived SVF for the treatment of alopecia.

3 Study Design

This is a prospective, non-randomized, non-blinded, interventional, consecutive series, multiple site study to determine initial safety and feasibility of a single injection of autologous adipose-derived SVF for the treatment of alopecia.

4 Study Population

4.1 Subjects

A total number of eight (8) subjects from a single population, i.e., patients who have been diagnosed with androgenetic alopecia, will be recruited.

4.1.1 Inclusion Criteria

1. Males and females 18 – 60 years of age and older that have been diagnosed with androgenetic alopecia.
2. Subjects will be in good health (ASA Class I-II) with a BMI < 35.
3. Must have at least a 2cm x 2cm spot on the scalp which shows evidence of alopecia without scarring or traumatic injury
4. Able and willing to make the required study visits.
5. Able and willing to give consent and follow study instructions.
6. Must speak, read and understand English

4.1.2 Exclusion Criteria

1. History of bleeding disorders, anticoagulation therapy that cannot be stopped 14 days prior to injection
2. Allergic to lidocaine, epinephrine, valium or sodium phosphate
3. Individuals with a propensity for keloids
4. Individuals with diminished decision-making capacity will not be included in this research study
5. Current use of anti-inflammatory or anticoagulation medications that affect bleeding or are for bleeding disorders. These include: Plavix, Warfarin (Coumadin, Jantoven, Marfarin). In addition, if any of the following medicines are used two (2) weeks prior to surgery the patient will be ineligible.
6. Use of concomitant treatments, including topical medications, oral medications, meso-therapy, non-ablative fractional laser treatment, low-level laser therapy, interfollicular PRP injection and hair transplantation within the preceding 6 months.
7. All smokers and other tobacco users.

4.2 Study Site Selection

A maximum of three sites will participate in clinical data collection. The subjects will be divided equally among the sites as much as possible.

4.3 Concomitant Medications

If the subject is taking any medications on this list, it should be discontinued two (2) weeks prior to surgery, and only Tylenol should be taken for pain. All other medications must be

specifically cleared by the doctor prior to surgery. It is absolutely necessary that all current medications be specifically cleared by the doctor and the nursing staff.

ADVIL	CP-2 TABLETS
ALCOHOL	DARVON WITH ASA PULVULES
ALEVE	DARVON COMPOUND PULVULES
ALKA SELTZER (EFFERVESCENT Tablet)	DARVON COMPOUND 65
ALKA SELTZER (COLD MEDICINE Tablet)	DARVON N WITH ASA
ANACIN TABLETS AND CAPLETS (MAXIMUM STRENGTH)	DASIN CAPSULES
ARTHRALGEN TABLETS	DAYPRO
ARTHRITIS STRENGTH BUFFERIN TABS	DINOL TABLETS
ARTHROPAN LIQUID	DISALCID CAPSULES
ARTHROTEC	DOAN'S PILLS
ASA TABLETS ENSEALS	DUOPRIN'S SYRUP
ASCRIPTIN WITH CODEINE	DUOPRIN CAPS
ASCRIPTIN TABLETS	DURADYNE TABLETS
ASCRIPTIN AD TABLETS	DYNOSAL TABLETS
ASCRIPTIN EXTRA STRENGTH	EASPRIN
ASPIRBUF TABLETS	ECOTRIN TABLETS
ASPERGUM	EFFICIN TABLETS
AXOTAL TABLETS	EFFICIN WITH CODEINE TABLETS
BAYER ASPIRIN TABLETS	EQUAGESIC TABLETS
BAYER CHILDREN'S COLD TABLETS	EXCEDRIN TABLETS AND CAPS
BAYER CHILDREN'S ASPIRIN TABLETS	EASPRIN
BC TABLET AND POWDER	ECOTRIN TABLETS
BUFF-A COMP #3 TABLETS WITH CODEINE	FENOPROFEN
BUFFAPRIN TABLETS	FIORINAL TABLETS
BUFFERIN TABLETS	FIORINAL WITH CODEINE
BUFFERIN ARTHRITIS STRENGTH TABLETS	FOUR-WAY COLD TABLETS
BUFFERIN EXTRA-STRENGTH TABLETS	GAYSAL-S TABLETS
BUFFERIN WITH CODEINE #3 TABLETS	GEMISIN TABLETS
BUFFETS II TABLETS	GOODY'S HEADACHE POWDER
BUF-TABS	HYDROCODONE (VICODIN, LORTAB, NORCO)
CAMA ARTHRITIS PAIN RELIEVER	IBUPROFEN
CELEBREX	INDOMETHACIN
CODEINE	INDOCIN
CONGESPRIN CHEWABLE TABLETS	INDO-LEMMON CAPSULES
COPE TABLETS	LANORINAL TABLETS
COSPRIN TABLETS	MAGAN TABLETS
COUMADIN	MAGSAL TABLETS
	MARNAL CAPS
	MAXIMUM BAYER ASPIRIN
	MEASURIN TABLETS
	MEDIPREN
	MEFENAMIC ACID
	MIDOL CAPLETS

METHOCARBAMOL WITH ASPIRIN
TABLETS
MECLOMEN
MECLOFENAMATE
MICRAININ TABLETS
MOBDIN TABLETS
MOBIGESIC TABLETS
MOMENTUM MUSCULAR BACKACHE
MOTRIN, FORMULA TABLETS
NALFON
NAPROSYN
NAPROXEN
NEOCYLATE TABLETS
NORGESIC & NORGESIC FORTE
TABLETS
NUPRIN
ORUDIS
OS-CAL GESIC TABLETS
PABLATE
PABLATE-SF TABLETS
PEPTO BISMOL TABLETS AND
SUSPENSION
PERCODAN & PERCODAN-ASA DEMI
TABLET
PERSISTIN TABLETS
PLAVIX
PROPOXYPHENE COMPOUND 65

PIROXICAM (FELDENE)
PLAVIX
ROBAXISAL TABLETS
RUFEN
S-A-C TABLETS
ST. JOESPH ASAPIRIN FOR CHILDREN
ST. JOESPH COLD TABLETS FOR
CHILDREN
SINE-OFF SINUS MEDICINE TABLETS
SK-65 COMPOUND CAPS
STANBACK TABLETS AND POWDER
SUPAC CAPS
SYNALGOS CAPS
SYNALGOS-DC CAPSULES
TALWIN COMPOUND TABLETS
TRENDAR
TOLECTIN
TRIAMINICIN TABLETS
TRIGSESIC
TRILISATE TABLETS & LIQUID
ULTRAM
URACEL
VANQUISH
VERIN
VITAMINE SUPPLEMENT
VOLTAREN
ZORPRIN TABLETS

5 Study Visits and Methods

5.1 Study Measurements

5.1.1 Safety

All adverse events will be recorded and evaluated for severity.

5.1.2 Feasibility

Before the procedure the density (number of hairs per square centimeter) and thickness (mm) of the hair will be measured and compared to the same measurements after the procedure at 3 and 6 months.

5.2 Study Visit and Procedures

5.2.1 Visits

There will be between 7 and 8 study visits for each subject (screening and pre-surgery 1 may be combined). Each office visit will take approximately 0.5 hour. The procedure visit will be conducted at the same center on an outpatient basis.

5.2.2 Recruitment

Subjects will be recruited via; 1) email utilizing a list of patients that have given their prior consent to be contacted in this manner 2) at the PI's office when they come in for their regularly scheduled appointments 3) referrals from healthcare professionals within the community or 4) via IRB approved flyers. Subjects recruited via email or flyer will be requested to call in for more information. Designated office staff will screen subjects in the office or on the phone to evaluate eligibility.

5.2.3 Informed Consent & HIPAA

The Consenting Process will only be done by the PIs or other qualified consent designees. The PI or consent designee will conduct a complete interview for each potential Subject. The PI and authorized consent designees have clinical experience, have completed either CITI and/or NIH training "Protecting Human Research Participants", and have individual expertise and training detailed in their respective curriculum vitae or resumes.

The PIs and authorized consent designees will describe the project, its goals, expectations of the study, description of inclusion/exclusion criteria for the participants, the liposuction surgery, fat processing to obtain cells, scalp injections, events at the study visits, questionnaires to be used, that their participation has potential (but not guaranteed) direct medical benefit to them, and that the study may provide new knowledge relevant to potential use of cells or tissue therapies in the future. Each subject must be informed that participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical treatment or relationship with the treating physician.

The PI or consent designee will review the elements of HIPAA and Protected Health Information (PHI) with each participant and each participant will be asked if s/he understands HIPAA authorization and PHI. Each participant will be asked to voluntarily sign a study Informed Consent Form and HIPAA Authorization Form before any study-related procedure is performed. The subject will sign the consent form if willing to proceed or decline any further participation if unwilling. Informed Consent Forms must be dated and signed by the PI or consent designee and participant or the participant's legal representative and the original signed consent form kept by the Investigator in the study patient's file. "Legal representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a

prospective participant to the participant's participation in the procedure(s) involved in the research. A copy of the signed consent documents will be provided to each subject.

5.2.4 Enrollment

The subject will be assigned an anonymous, unique identifier called the Subject ID unrelated to the subject's name from a list of possible ID's. The subject's name and corresponding identifier will be recorded in a study look up document, which shall be kept at the study site.

The subject ID of excluded subjects will not be re-assigned. Information describing the reason(s) for exclusion will be documented on the Inclusion/Exclusion CRF.

5.2.5 Study Timeline

Initial Contact to Informed Consent – The timing from the initial contact and obtaining consent at the Pre-surgery #1 is expected to range from the same day up to two (2) weeks depending on participant and physician availability. Potential Participants will have the option of taking additional time to review the documents, but it is expected that the dates for surgery will be set within two to four weeks depending on scheduling. A potential Participant will need to have all documents signed and in place prior to surgery and if they choose to participate in the project the study documents will be included in the package.

5.2.6 Methods

1. Liposuction will be performed at the clinical site according to standard clinical practice.
2. The surgery and scalp injection will be conducted on the same day within 1.5 hours from collection of adipose to injection in the scalp.
3. At the conclusion of the fat harvest procedures, support garments and dressings are worn by the Subject to control swelling and promote healing.
4. Processing of the fat will be done immediately after harvest using a sterile single use disposable (GID SVF-2) and according to the instructions for use with the device. The GID SVF-2 is an investigational device and will be labeled as such.
5. Injection of Cells into Scalp
The scalp will be cleansed with 70% alcohol, and 1% lidocaine will be injected as a regional nerve block. All of the SVF will be injected under the scalp at the superficial subcutaneous plane in a 2 x 2 cm area.
6. Hair Measurements

Refer to the Hair Measurement CRF for location of 2 x 2 cm area. Hair measurement will be made using a computerized handheld USB camera at baseline and 3 and 6 months after treatment.

5.2.7 Adverse Events

Although the actual study poses no threat or risk above that for the liposuction/fat harvesting procedure and scalp injection, any Adverse Event or Serious Adverse Event experienced by a participant involved in the study, whether or not due to the study, will be reviewed and evaluated for appropriate follow-up actions (see Adverse Events, Side Effects and Other Risks, Section 6). An Adverse Event Form or Serious Adverse Event Form will be filled out if such an event occurs and communicated directly to the Sponsor within 3 days.

5.2.8 Data Collection

The investigator will train his/her study personnel regarding the study protocol. This training will take place prior to enrollment of the first subject. The study site shall maintain applicable regulations specific to the conduct of clinical studies. Steps will be taken in the planning and implementation of this study to ensure that the data collected are accurate, consistent, complete and reliable.

During the study, patient data paperwork will be kept using standard patient records criteria, confidentiality and information security procedures that include limited access, Co-PI oversight of records, and secured files. The data will be stored consistent with the clinics Records Retention Policies.

5.2.9 Case Report Forms

All clinical data obtained will be recorded on source documents (i.e. study chart) and information required by the protocol will be copied onto the case report forms (CRFs). CRFs for each subject enrolled in the study will be stored in a binder. The appropriate CRFs will be completed and signed by the PI. All CRFs will be completed in a legible manner in ink. Any corrections required will be made by drawing a single line through the incorrect entry, entering the correct information, and initialing and dating the change.

During the study, the quality of the data will be assured by the presence of site personnel who will check the CRFs against the site's source documents for completeness and to ensure that data is collected in adherence to the protocol. Evident recording errors will be rectified by the clinical site.

5.2.10 Data Management and Quality Control

A clinical study database will be generated by The GID Group, Inc. and/or by their representative to record all clinical data from the CRFs. Deviations, discrepancies and missing data will be investigated. After all protocol deviations and/or discrepancies are resolved and all corrections and clarifications are made to the database, the database is declared complete, accurate and locked.

Any missing, unused, or spurious data will be noted in the study report. Data may be disqualified if it meets the pre-determined exclusion criteria. Selection of the acceptable subjects for data analyses will be established prior to the database lock. A discussion of any outliers and reasons for excluding subjects or data will be documented and summarized in a study report.

5.3 Subject Exit and Study Completion Procedures

5.3.1 Subject Exit Status

Subjects shall exit the study with a status as one of the following:

1. **Completing**
One who completes all required study visits.
2. **Non-completing**
 - a. One who exits the trial by his or her own volition or at the discretion of the PI.
Any subject may decide to voluntarily withdraw from the trial at any time without prejudice.
 - b. Non-completions are to be characterized as:
 - i. One who does not complete all the study visits.
 - b. The particular reason for non-completion should be documented on the CRF.
3. **Termination**
Subjects may be terminated from the study at the discretion of the PI only for reasons related to the study examinations that would jeopardize the subject's health and/or welfare if they were to continue in the study.

5.3.2 Completed Study

The trial is completed when the planned enrollment has been completed, and the enrolled subjects exit the study.

6 Side Effects, Adverse Events and Other Risks

The Study adds no expected risks or the need for additional safety precautions for the Subject beyond what they would have for the standard Liposuction surgery and scalp injection. These are detailed in the INFORMED CONSENT - LIPOSUCTION (Suction-Assisted Lumpectomy Surgery) and the CONSENT FOR SCALP INJECTION PROCEDURE.

Throughout the course of the proposed study, all efforts will be made to remain alert to possible adverse events or untoward findings. If an adverse event occurs, the first concern will be the safety of the subject. Appropriate medical intervention will be made. Any adverse events observed by the investigator or reported by the subjects, regardless of severity and whether or not ascribed to the research procedures, will be recorded in the appropriate section of the subject's CRF. Any subjects who are terminated from the study due to adverse events will be followed until their medical outcome is determined.

7 Statistical Analysis

7.1 Sample Size

This is a pilot study with a sample size of N=8 participants.

7.2 Statistical Methods

Hair density and thickness will be compared pre and post treatment. The data gathered will be used to establish a baseline difference for future studies.

7.3 Procedure for Accounting for Missing, Unused or Spurious Data

Any missing, unused, or spurious data will be noted in the study records. Data may be removed if it does not meet quality criteria.

8 Ethical and Regulatory Considerations

This study must be carried out in compliance with the protocol and in accordance with the site's standard operating procedures. These are designed to ensure adherence to Good Clinical Practice (GCP) guidelines, as described in:

- Code of Federal Regulations, Title 21, Parts 50, 56, and 812.
- World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects 2013.
- ICH E6 Good Clinical Practice April 1996

The investigator agrees, when signing the protocol, to adhere to the instructions and procedures described in it and thereby to adhere to the principles of GCP to which it conforms.

8.1 Institutional Review Board

Initiation of this study requires approval by a qualified, properly constituted Institutional Review Board (IRB). The protocol, proposed informed consent form and subject recruitment material must be included in this review process and approved. A copy of the IRB approval will be kept in the study binder.

8.2 Protocol Reviews

The study will not be started until the Protocol and the Consent Form have been approved by the appropriate IRB. It is the responsibility of the Investigator to keep copies of written approvals and a list of the members of the IRB, their titles and their institutional affiliations in the study binder. The approval should include study identification and the date of review.

8.3 Protocol Amendments

If the Investigator desires to modify the procedures and/or design of the study, he or she must contact and obtain the consent and approval regarding the proposed changes from the IRB, where applicable.

8.4 Subject Information and Informed Consent

It is the responsibility of the Investigator to ensure that each subject (or legally authorized representative) receives an explanation of the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits involved and any discomfort it may entail. Each subject must be informed that participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical treatment or relationship with the treating physician.

It is the responsibility of the investigator at each study site to obtain a signed copy of the following consent documents from all subjects (as applicable) prior to enrollment into the study:

- Subject Informed Consent and
- HIPAA consent form

The Investigator will acknowledge the receipt of informed consent documents by also signing the forms where designated. A copy of each of the signed consent documents should be provided to the subject. The original consent documents should be filed by each Investigator for possible review for study monitoring or auditing purposes. Any changes to the informed consent and subject recruitment material must be approved by the IRB. A copy of the approved version(s) must be kept in the study binder after IRB approval.

8.5 Study monitoring

The GID Group, Inc. will provide study monitoring to assure clinical research quality.

8.6 Additional Considerations

The proposed study is subject to all applicable governmental rules and regulations concerning the conduct of clinical trials on human subjects. This includes, but is not necessarily limited to, the approval of an IRB (where applicable); obtaining prospective informed consent; monitoring of the conduct of the study and the completeness of the CRFs; and record retention in accordance with 21 CFR Part 812 Subpart G—Records and Reports.

It is the responsibility of each Investigator to obtain IRB approval of the study protocol and to keep the IRB informed of any serious side effects, any adverse events or any amendments to the protocol.

All correspondence with the IRB will be filed in the study binder.

9 References

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9. Fukuoka H, Suga H. Hair Regeneration Treatment Using Adipose-Derived Stem Cell Conditioned Medium: Follow-up With Trichograms. *Eplasty*. 2015;15:e10.