

**Evaluating the efficacy and safety of Embella® (Deoxycholic acid, produced by Espad  
Pharmed Darou Company) for the treatment of flank fat**

Protocol Revision Number: 1.1

Date: 24/01/2024

Confidential

The information contained in this document is the property of Espad Pharmed Darou Company. The contents of this document must not be disclosed, except to study investigators, responsible personnel, regulatory authorities, and the ethics committee, without written permission from Espad Pharmed Darou Company, unless required to the extent necessary for obtaining informed consent from individuals who may potentially be prescribed the product.

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## **1 Confidential Information**

Confidential information contained in this current document is provided to you, as the investigator and sponsor, for your review, as well as for review by your colleagues and the Ethics Committee (IRB/IEC). By accepting this document, you agree that the information contained herein will not be disclosed to others without written permission from Espad Pharmed Darou Company and the principal investigator of the study, except to the extent necessary for obtaining informed consent from individuals to whom the product will be administered. By signing the section below, the investigator commits to adhering to the specified terms of the protocol and also undertakes that any changes to the protocol must be approved by Espad Pharmed Darou Company prior to obtaining approval from the Ethics Committee.

Principal Investigator:

Name and Surname: Dr. Kamran Balighi

Position: Faculty Member at Tehran University of Medical Sciences and Health Services

Stamp and Signature:

Date: ...../...../.....

Sponsor Representative:

Name and Surname: Dr. Hamidreza Kafi

Position: Medical Unit Director of Orchid Pharmed Company, representing Espad Pharmed Darou Company

Signature:

Date: ...../...../.....

## 2 Abbreviations

ADR	Adverse Drug Reaction
AE	Adverse Event
ANOVA	Analysis of Variance
ASIS	Anterior Superior Iliac Spine
BMI	Body Mass Index
CD36	Cluster of Differentiation 36
CRP	C-reactive protein
FDA	Food and Drug Administration
GAIS	Global Aesthetic Improvement Scale
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
IQR	Interquartile Range
IRCT	Iranian Registry of Clinical Trials
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
PT	Preferred Term
SAE	Serious Adverse Event
SD	Standard Deviation

### **3 General Information (Administrative Information)**

#### **3.1 Scientific Title of the Study**

Evaluating the efficacy and safety of Embella (Deoxycholic acid, produced by Espad Pharmed Darou Company) for the treatment of flank fat

#### **3.2 Study Registration**

- Ethics Code:
  - Name of University of Medical Sciences/Name of Institution: Tehran University of Medical Sciences  
Code: IR.TUMS.MEDICINE.REC.1402.700  
Date: 04/03/2024
- Study Registration Code in the Iranian Registry of Clinical Trials (IRCT):  
IRCT20240416061507N1

#### **3.3 Date and Revision Number of the Protocol**

Protocol Revision Number: 1.1

Date: 23/08/2025

### **3.4 Specifications, Roles, and Responsibilities**

Sponsor: Espad Pharmed Darou Company

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Name and Surname: Dr. Hamidreza Kafi, Medical Unit Director of Orchid Pharmed Company, representing Espad Pharmed Darou Company

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Stamp and Signature:

Roles and Responsibilities:

- ✓ Preparation of the Final Draft of the Protocol
- ✓ Development of Study Booklet Forms
- ✓ Obtaining the necessary permits from foreign organizations for conducting the study
- ✓ Provision of the protocol and other necessary training courses for the medical center staff
- ✓ Provision of study-related expenses for participants, if necessary.
- ✓ Assessment of the facility's capabilities for implementation and continuation of the study, and undertaking necessary measures to provide them (ensuring an adequate number of consent forms and other materials required for the execution of the study)
- ✓ Review of Booklet Forms
- ✓ Preparation of a Report on Cases of Non-Conformity and Site Requirements, and Submission to Company Management
- ✓ Non-disclosure of the information contained in the protocol and study data without written permission from the principal investigator of the study
- ✓ Provision of financial support for all activities anticipated in the study protocol through the establishment of contracts with the investigators.

- ✓ Analysis and Interpretation of Results

**Principal Investigator Information:**

Name and Surname: Dr. Kamran Balighi

Education and Specialty: Dermatology Specialist

Position: Faculty Member at Tehran University of Medical Sciences and Health Services

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Stamp and Signature:

Date: ...../...../.....

**Roles and Responsibilities:**

- Conducting the study in accordance with the protocol approved by the Ethics Committee
- Establishment of a Team for Conducting the Study
- Holding training sessions for new and current team members whenever necessary
- Approval and supervision of the appropriate site for product storage
- Approval and Supervision of an Appropriate Site for Candidate Admission
- Non-disclosure of the information contained in the protocol and study data without written permission from Espad Pharmed Darou Company (except to the extent necessary for obtaining informed consent from individuals for whom the product will be prescribed).

**Details of the Participants Recruitment Center and Principal Investigators at Each Center:**

**1. Name and Surname: Dr. Kamran Balighi**

Position: Faculty Member and Professor at Tehran University of Medical Sciences and Health Services

Education and Specialty: Dermatology Specialist

Patient Admission Center: Razi Specialized Dermatology Hospital

Workplace Address: Razi Specialized Dermatology Hospital, Razi Alley, Vahdat Eslami Square, Vahdat Eslami Street, Tehran, Iran

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2. Name and Surname: Dr. Navid Namaki Zadeh Esfahani

Position: Doctor of Medicine (MD)

Education and Specialty: Doctor of Medicine (MD)

Patient Recruitment Center: Razi Specialized Dermatology Hospital

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Contact Phone Number: +98 21 5563 0553

#### Roles and Responsibilities:

- Conducting the study in accordance with the protocol approved by the principal investigator and ethics committees.
- Establishment of a Team for Conducting the Study at the Participants Recruitment Site
- Non-disclosure of the information contained in the protocol and study data without written permission from Espad Pharmed Darou Company and the principal investigator of the study (except to the extent necessary for obtaining informed consent from individuals for whom the product will be prescribed).
- Holding training and practice sessions for new and current team members whenever necessary
- Preparation of an Appropriate Site for Participants Admission
- Preparation of an appropriate location for the storage of products used in the study

#### Principal Investigators' Details at the Center:

- Razi Specialized Dermatology Hospital

Contact Address: Razi Specialized Dermatology Hospital, Razi Alley, Vahdat Eslami Square, Vahdat Eslami Street, Tehran, Iran

Telephone: +98 21 5288 8282

- Collaborating investigators at this site who are involved in patient recruitment and performing the duties of a "collaborating investigator":

- 1- Dr. Kamran Balighi – Faculty Member and Professor at Tehran University of Medical Sciences and Health Services
- 2- Dr. Namakizadeh – Doctor of Medicine (M.D.)

### 3.5 Introduction

With the increasing demand for body contouring, non-invasive or minimally invasive methods for reducing localized fat in various areas of the body have gained growing popularity over the past decade (1). Localized adipose deposits are typically found in regions such as the abdomen, flanks, thighs, inner knee, arms, and others. Although diet, exercise, and bariatric surgery may be effective in controlling obesity, aesthetic procedures remain necessary for the removal or reduction of localized fat deposits in areas resistant to these interventions, such as the flanks and abdomen. Liposuction is the most common method for reducing excess localized fat; however, as an invasive surgical technique, it is associated with complications such as pain, infection, prolonged recovery, scarring, hematoma, deep vein thrombosis, pulmonary embolism, and anesthesia-related adverse effects. These complications, along with the extended recovery period, have led patients to seek alternative, less invasive methods for body contouring. Currently, non-invasive fat reduction techniques include low-level lasers, radiofrequency, ultrasound, infrared light, cryolipolysis, and the use of injectable solutions containing fat-dissolving agents. Treatments that are minimally invasive and not accompanied by the aforementioned complications are ideal for patients seeking reduction of localized fat for body contouring (2).

Multiple clinical trial studies have been reported in the field of adipose tissue reduction through subcutaneous injection of solutions containing phosphatidylcholine and bile salts, specifically sodium deoxycholate, and consequently, these treatments have gained significant popularity. Studies have demonstrated that deoxycholate is the primary active ingredient in the aforementioned injectable solutions and is responsible for the clinical reduction of adipose tissue (3).

Synthetic purified deoxycholic acid has been introduced as the first pharmacological intervention approved by the FDA for the reduction of submental fat. Deoxycholic acid is a type of bile acid which, due to its ability to induce non-selective cell lysis and disruption of adipocyte membranes (adipocytolysis), leads to the emulsification of fat in the intestine (4,5). Deoxycholic acid has been used for the reduction of localized fat for three decades. Its mechanism of action involves the emulsification of phospholipids and subsequent dissolution of biological membranes, which leads to adipocyte necrosis. In a prospective study conducted in 2017, the efficacy and safety of a 1.25% sodium deoxycholate solution were evaluated in 221 patients with various forms and degrees of localized fat. Injections were administered into the adipose tissue at 6-week intervals and continued until clinical results were achieved.

Outcomes were assessed using before-and-after photographs and patient satisfaction was measured by completion of an anonymous form, while adverse events (AEs) were reported by the treating physician. Among 185 patients eligible for final evaluation, the mean treatment efficacy score reported by patients was 7.4, and medical assessment indicated treatment success in 93.5% of cases. AEs were mainly mild and localized at the injection site, with the incidence of severe complications being very rare. The results of this study confirm the efficacy and safety of deoxycholic acid injections for the reduction of localized fat (6).

In another study, the efficacy and safety of deoxycholic acid injection in the abdominal area were evaluated in 7 female patients. The results indicate that its mechanism of action is through the increase of crown-like structures and macrophage infiltration, as well as the reduction of leptin expression, hormone-sensitive lipase, triglyceride lipase, and CD36, ultimately resulting in adipose tissue necrosis. In the evaluation of systemic inflammatory markers, including CRP, lipid profile, and blood glucose, no significant changes were observed (7).

In another study, with an emphasis on the effect of deoxycholic acid in reducing the volume of submental adipose tissue, new sites for its injection were proposed. This study reported that deoxycholic acid can be used as an alternative method in areas where other interventions, such as liposuction, do not have acceptable efficacy or safety. In this study, smaller areas of fat accumulation, such as the axilla, upper arm, and around the knee, were suggested for further investigation in future studies. Additionally, the injection of modified concentrations of deoxycholic acid in larger areas, such as superficial abdominal fat, may be beneficial (8).

In a study aimed at reducing local pain and inflammation caused by deoxycholic acid injection, a combination of deoxycholic acid with lidocaine and triamcinolone was used. The resulting solution was injected at one-centimeter intervals into the medial aspect of the right thigh of one patient and the distal regions of both arms of a second patient. Additionally, undiluted deoxycholic acid solution was injected as a control into the medial aspect of the left thigh of the first patient. The results of the evaluation in two cases indicated that the use of this method was effective for larger areas by increasing the spreadability and tolerability, and was associated with lower consumption of deoxycholic acid and fewer side effects (9).

The first successful case report of deoxycholic acid injection for the reduction of flank fat in the United States was published in 2018. In this study, a 39-year-old male received deoxycholic acid injections with a total volume of 4 cc (2 cc on each side) in the flank fat area. Follow-up at 12 weeks demonstrated a gradual reduction of fat in this region, and no recurrence of fat accumulation was observed at the 12-month follow-up. The patient was completely satisfied with the outcome (10).

Given that non-invasive methods have subtle effects that are not immediately observable, various objective and subjective techniques are utilized to assess their efficacy. In most studies, measurement of the circumference of the target area before and after the intervention is reported as an indicator. Other objective techniques, such as the use of calipers, ultrasound, MRI, and three-dimensional photography, have also been employed. Common subjective methods include the evaluation of standardized photographs by a blinded assessor and patient satisfaction surveys. All existing methods for quantifying non-invasive fat reduction have significant limitations and cannot be relied upon independently (11).

## **4 Study Objectives and Hypotheses**

### **4.1 Study Hypothesis:**

The injectable solution containing deoxycholic acid (Embella, manufactured by Espad Pharmed Darou Company) demonstrates appropriate efficacy and safety in the reduction of lateral abdominal fat.

### **4.2 Primary Objective:**

The aim of this study is to determine the efficacy and safety of the injectable solution containing deoxycholic acid (Embella, manufactured by Espad Pharmed Darou Company) in reducing fat in the flank area.

### **4.3 Secondary Objectives:**

- The proportion of participants who, at week 6, according to the investigator's assessment on the GAIS score, have achieved a score of 1 or higher (improved, much improved, or very much improved).
- Changes from baseline in waist circumference at weeks 6 and 12 using a flexible measuring tape.
- Changes from baseline in body weight at weeks 6 and 12.
- Changes from baseline in right and left thigh circumference at weeks 6 and 12 using a flexible measuring tape.
- Changes from baseline in flank fat on each side measured by caliper at weeks 6 and 12.

- Assessment of the trend in dermal and hypodermal thickness changes on both sides by measurement with ultrasonography from baseline to weeks 6 and 12
- Assessment of participants' satisfaction at weeks 6 and 12
- Assessment of the incidence of AEs following treatment

## 5 Study Design and Methodology

### 5.1 Study Population:

- **Inclusion Criteria:**

1. Men and women aged between 21 and 65 years
2. Presence of mild to moderate flank fat, as assessed by the investigator and ultrasound and/or caliper (with a thickness of  $\geq 2$  cm of adipose tissue at the posterior axillary lines at the level of the ASIS).
3. Signing of the informed consent form by the participants
4. Ability to comply with study instructions and likelihood of completing all required visits
5. Agreement to abstain from any treatment in the flank area, including botulinum toxin, hyaluronic acid fillers, cosmetic surgery, laser/light therapy, chemical peels, etc., throughout the study period.

- **Exclusion Criteria:**

1. Planning for lifestyle modification during the predicted duration of the study
2. History of liposuction or laser lipolysis surgery within the past 12 months, or intention to undergo these procedures
3. Significant weight loss in the past 6 months or planned weight loss during the anticipated duration of the study
4. Body mass index (BMI) greater than  $30 \text{ kg/m}^2$
5. Waist circumference greater than 105 centimeters
6. Affliction with uncontrolled systemic diseases
7. Severe cardiovascular diseases

8. Known hypersensitivity or allergy to the study product or its components
9. Pregnant women, breastfeeding women, or women who are expected to become pregnant during the anticipated duration of the study
10. Current enrollment in a drug or investigational device study, or participation in such a study within the past 30 days, as well as during the course of the study.
11. Previous treatment of the flank area with hyaluronic acid fillers or semi-permanent fillers within the past 12 months
12. Use of permanent fillers or silicone in the flank area
13. Individuals who intend to undergo cosmetic procedures in the treatment area during the study, or who have a history of cosmetic procedures (such as surgery) or visible scars in that area that may affect the assessment.
14. Individuals with volume loss due to trauma, adipose tissue disorders associated with autoimmune diseases such as generalized lipodystrophy (e.g., in juvenile dermatomyositis), localized lipodystrophy (such as Barraquer-Simons syndrome), hereditary diseases, or HIV-associated disease
15. Infection or skin diseases at the injection site
16. Evidence of recent alcohol or drug abuse
17. Medical and/or psychiatric conditions of such severity that they may interfere with the outcomes of the study
18. Having a known bleeding disorder or the use of medications that increase the likelihood of bleeding after injection
19. Presence of hair in the flank area that interferes with assessment or treatment
20. Predisposition to hypertrophic scar formation
21. History of anaphylaxis or allergy to lidocaine (or other amide anesthetics), hyaluronic acid products, or streptococcal proteins
22. Affliction with Porphyria
23. Presence of active inflammation, infection, malignant or premalignant lesion, or non-healed ulcer in the flank region

24. Having a condition or being in a situation which, in the opinion of the investigator, may place the individual at significant risk, disrupt the study results, or interfere with the individual's participation in the study.

- **Withdrawal Criteria:**

1. Withdrawal of participant from informed consent
2. Non-compliance, including refusal to adhere to the medical requirements of the study, failure to undergo procedures specified in the study protocol, or use of prohibited medications.
3. Inability to follow up on the participant's status
4. Treatment of the flank area with hyaluronic acid fillers or semi-permanent fillers during the course of the study
5. The use of any permanent filler or silicone materials in the flank area during the course of the study
6. Undergoing any cosmetic procedures in the treatment area during the study period (such as surgery)
7. Having conditions that, in the opinion of the investigator, may interfere with the assessment of efficacy

## **5.2 Study Outcomes and Methods of Assessment:**

### **Primary Outcome**

- The proportion of participants who, at week 12, according to the investigator's assessment on the GAIS score, have achieved a score of 1 or higher (improved, much improved, or very much improved).

### **Secondary Outcome(s)**

- The proportion of participants who, at week 6 based on the investigator's assessment on the GAIS score, have achieved a score of 1 or higher (improved, much improved, or very much improved).
- Changes from baseline in waist circumference at weeks 6 and 12 using a flexible measuring tape.
- Changes from baseline in body weight at weeks 6 and 12.
- Changes from baseline in right and left thigh circumference at weeks 6 and 12 using a flexible measuring tape.
- Changes from baseline in flank fat on each side measured by caliper at weeks 6 and 12.
- Assessment of the trend in dermal and hypodermal thickness changes on both sides by measurement with ultrasonography from baseline to weeks 6 and 12
- Assessment of participant satisfaction at weeks 6 and 12
- Assessment of the incidence of AEs following treatment

### 5.3 Study Schedule Table

	Study Duration			
	Screening	Intervention	Follow-up	
Time Point	Screening Visit	Visit 1	Visit 2	Visit 3
Time	Day -7 to -1	Day 0	Week 6 ± 1 week	Week 12 ± 1 week
<b>Informed Consent Form</b>	×			
<b>Assessment of Inclusion and Exclusion Criteria</b>	×			
<b>Medical History</b>	×			
<b>Physical Examination and Vital Signs</b>		×	×	
<b>Concomitant Medications</b>	×	×	×	×
<b>Skin Ultrasonography</b>	×		×	×
<b>Photography</b>		×*	×	×
<b>Intervention</b>		×	×**	
<b>GAIS Assessment</b>			×	×
<b>Assessment of Participant Satisfaction</b>				×
<b>Adverse Event Assessment</b>	×	×	×	×

\* Photography must be performed prior to injection.

\*\* In case a touch-up injection is deemed necessary by the physician.

## **6 Sample Size Calculation Method**

In this study, 30 participants will be enrolled.

### **6.1 Statistical Analysis**

#### **Study Profile**

All participants who sign the informed consent form will be included in the final statistical report. The participants flow throughout the study, reasons for withdrawal from the study, and major deviations and violations of the protocol will be reported.

#### **Primary Endpoint Analysis**

Participants who, in the GAIS score assessment by the investigator, received a score of 1 or higher will be reported with the number and percentage.

#### **Secondary Endpoint Analysis**

Descriptive analysis of data for quantitative variables will be reported as mean and standard deviation (SD) or median and interquartile range (IQR), based on the data distribution, and for qualitative variables as the number and percentage. Changes over time will be analyzed using repeated measures analysis of variance (repeated measures ANOVA) or the Friedman test, depending on the data distribution. Comparisons between baseline and subsequent timepoints will also be performed using the paired t-test or the Wilcoxon test, as appropriate. The significance level for the tests will be considered as 0.05.

#### **Adverse Events' Analysis**

AEs will be classified according to the MedDRA dictionary based on the Preferred Term (PT) and analyzed in terms of frequency and percentage. The severity and seriousness of each event will also be reported.

## **7 Harms**

#### **Adverse Events**

An AE is described as any occurrence that happens to a participant in the study and presents with clinical manifestations differing from the progression of baseline conditions. It does not necessarily have a causal relationship with the investigational treatment used in the study.

Clinical manifestations that will be reported as AEs include any symptom, sign (such as an abnormal laboratory result), or temporary illness associated with the use of the investigational product, regardless of whether a causal relationship with the product is suspected or not.

An adverse drug reaction (ADR) is described as a harmful response to a drug that occurs at doses normally used in humans for the prevention, diagnosis and treatment of diseases, or modification of a physiological function.

### **Classification of AEs Based on Severity**

The severity of AEs is classified by the physician's assessment as mild, moderate, or severe.

### **Classification of AEs Based on Seriousness**

An event is considered a serious adverse event (SAE) if:

- Results in death.
- Is life-threatening or results in a risk of death.
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity.
- Is a congenital anomaly/birth defect.
- Results in a condition requiring special clinical intervention for the participant.

### **Adverse Event Reporting**

All AEs, including both serious and non-serious AEs that occur following administration of the product, shall be precisely documented. The description of the event, its chronological sequence relative to the time of product administration, its duration, the processes utilized for its diagnosis, and the outcomes of any re-exposure to the product must be recorded. Furthermore, a qualitative assessment of the AE, conducted by the investigator based on its severity and its relationship to the administered product, must also be documented.

## **8 Ethical Considerations and Dissemination of Results**

### **8.1 Ethics Committee Approval**

- Ethics committee approval is mandatory prior to the initiation of this study.
- No participants will be enrolled in the study without providing informed consent.
- All participants will be informed that they may withdraw from the study at any time and without providing any explanation, should they so wish.
- AE report forms will be evaluated during the study. The study research team is responsible for the prompt review of any AE that occur (regardless of whether the event is directly attributable to the investigational drug or not).

## **8.2 Informed Consent Form**

During the screening of participants for study enrollment and prior to any procedures, the investigator shall fully explain the purpose and details of the study to the participants in clear and simple language. After answering any potential questions, sufficient time and opportunity will be provided to the participants to inquire about the study details so that they can decide whether or not to participate in the study. Additionally, the study investigator will explain to the participants that they are free to refuse the use of their information or to withdraw from the study at any time and for any reason.

When the information provided to the participants has been understood by them and the requested explanations have been given to the participants, the participants is given sufficient time to sign the informed consent form and to write their first and last name on the consent form. The investigator physician shall also stamp and sign the relevant consent form. For each participants, two copies of the consent form, stamped and signed by both the physician and the participants, are prepared; one copy is given to the participants and the other copy remains at the site and with the investigator. The investigator and the study sponsor may, at any time and for operational reasons, withdraw the participants from the study. Any other necessary information to fully protect the human rights of the participants, in accordance with GCP guidelines, local and national regulations for conducting clinical studies, and the Declaration of Helsinki, will also be explained.

## **8.3 Method of Results Dissemination**

Any dissemination of results prior to the initial publication shall be unauthorized. Any subsequent presentation or publication of results (including sub-studies) by any member of the study team must be approved by the principal investigator and the sponsor, and reference must be made to the study and the initial publication of the data. The final decision regarding the publication of any version/summary/presentation will be made by the principal investigator of the study and the sponsor.

## 9 References:

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