

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of safety and effectiveness of an injectable solution containing deoxycholic acid with the brand name ®Embella, in order to reduce submental fat.

Protocol summary

Study aim

Evaluation of safety and effectiveness of an injectable solution containing deoxycholic acid with the brand name ®Embella, in order to reduce submental fat.

Design

Single group, phase 2, before -after clinical study. sample size is 20.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 volunteers with unwanted submental fat with moderate to severe intensity will be selected and enrolled in the study after signing consent form. Participants will be treated for one to three Injection sessions with ®Embella solution. Before intervention, 4 and 12 weeks after last injection changes in submental fat, diameter of submental area and satisfaction of participants will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 18 to 65, People with unwanted submental fat with moderate to severe intensity, grades 2 and 3 of the clinical grade of SMF (submental fat) evaluation, have signed the informed consent form and agree to a 3-month follow-up. Exclusion criteria: Any previous intervention to treat submental fat, Specific anatomical features or previous damage to the intervention site (ulcers, liposuction, difficulty swallowing, enlargement of the thyroid gland or lymph nodes) that interfere with the evaluation of intervention results, History of dysphagia.

Intervention groups

Intervention group: At least one and maximum of 3 sessions of treatment with 2 ml of Embella® injectable solution contains 20 mg deoxycholic acid with a minimum interval of 4 weeks.

Main outcome variables

Grading changes in submental fat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N29**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and effectiveness of an injectable solution containing deoxycholic acid with the brand name ®Embella, in order to reduce submental fat.

Public title

Evaluation of an injectable solution with the brand name ®Embella in order to reduce submental fat.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 65 People with unwanted submental fat with moderate to severe intensity, grades 2 and 3 of the clinical grade of SMF (submental fat) evaluation Have signed the informed consent form and agree to a 3-month follow-up.

Exclusion criteria:

Any previous intervention to treat submental fat. Specific anatomical features or previous damage to the intervention site (ulcers, liposuction, difficulty swallowing, enlargement of the thyroid gland or lymph nodes) that interfere with the evaluation of intervention results. History of dysphagia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.102

Health conditions studied

1

Description of health condition studied

Submental fat

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Grading changes in submental fat

Timepoint

Before intervention, 4 and 2 weeks after last injection

Method of measurement

Standard grading evaluation of submental fat (SMF)

Secondary outcomes

1

Description

Change in fat diameter of submental area.

Timepoint

Before intervention, 4 and 2 weeks after last injection

Method of measurement

Caliper

2

Description

Consumer Satisfaction

Timepoint

Before intervention, 4 and 2 weeks after last injection

Method of measurement

Using the Likert scale includes: 0 = not satisfied at all, 1 = slightly satisfied, 2 = moderately satisfied, and 3 = very or extremely satisfied

Intervention groups

1

Description

Intervention group: At least one and maximum of 3 sessions of treatment with 2 ml of Embella® injectable solution contains 20 mg deoxycholic acid with a minimum interval of 4 weeks. The product is 2 ml of

sterilization transparent and colorless vials free of visible particles containing 20 mg deoxycholic acid. Other compounds include hyaluronic acid, injectable water, sodium chloride, sodium hydroxide, hydrochloric acid and anhydrous disodium phosphate.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

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No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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dermalab@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zist orchid pharmed Company

Full name of responsible person

Araz Sabzevari

Street address

No 42, Atar squer, Atar street, Valie-asr street, Vanak squer

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Email

ask@orchidpharmed.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zist orchid pharmed Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mansour Nassiri Kashani

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Dermatology

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Province

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable