Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address

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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1994766411

Phone

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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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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