Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A phase IV single-arm clinical trial to evaluate the safety and satisfaction of AbobotulinumtoxinA (Lucentra®) in the treatment of upper facial wrinkles

Protocol summary

Study aim
The objectives of this study are to assess safety, and subject satisfaction of Abobotulinum toxin A (Espad Pharmed)
Design
The study is designed as phase IV, single-armed, prospective study
Settings and conduct
A phase IV single-arm clinical trial to evaluate the safety and satisfaction of AbobotulinumtoxinA (Lucentra®) in the treatment of upper facial wrinkles this study will be performed during 120 days for each participants.
Participants/Inclusion and exclusion criteria
1. Male or female ≥18 to ≤65 years of age 2. Willingness for signing and having signed the informed consent form 3. Indication of treatment with botulinum toxin type A in the upper face Exclusion criteria: 1. Previous treatment with botulinum toxin type A, fillers, skin abrasions, or photo rejuvenation in the upper face 4 months prior to study 2. Any condition or circumstance that might pose a risk to the subject or interfere with the ability to acquire satisfactory clinical data 3. Pregnancy or breast-feeding
Intervention groups
All the participants received a single administration of Abobotulinumtoxin A (dose and injection sites per standard practice). Touch-up at Day 14 allowed at the investigator's discretion.
Main outcome variables
Safety participant satisfaction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150303021315N39**
Registration date: **2025-10-30, 1404/08/08**
Registration timing: **prospective**

Last update: **2025-10-30, 1404/08/08**
Update count: **0**
Registration date
2025-10-30, 1404/08/08

Registrant information
Name
Nassim Anjidani
Name of organization / entity
Orchid Pharmed
Country
Iran (Islamic Republic of)
Phone
+98 21 4347 3000
Email address
amini@orchidpharmed.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-01, 1404/08/10
Expected recruitment end date
2026-03-30, 1405/01/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A phase IV single-arm clinical trial to evaluate the safety and satisfaction of AbobotulinumtoxinA (Lucentra®) in the treatment of upper facial wrinkles

Public title

Phase IV study of Lucentra® (Espad pharmed)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female ≥18 to ≤65 years of age Willingness for signing and having signed the informed consent form Indication of treatment with botulinum toxin type A in the upper face

Exclusion criteria:

Previous treatment with botulinum toxin type A, fillers, skin abrasions, or photo rejuvenation in the upper face 4 months prior to study Any condition or circumstance that might pose a risk to the subject or interfere with the ability to acquire satisfactory clinical data 3. Pregnancy or breast-feeding

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

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 Tehran University of Medical Sciences

Street address

Central Building of TUMS, Ghods Ave,Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

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Postal code

1417653761

Approval date

2025-10-14, 1404/07/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.444

Health conditions studied

1

Description of health condition studied

Upper face wrinkles

ICD-10 code

L98.8

ICD-10 code description

Other specified disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

Evaluation of AbobotulinumtoxinA safety

Timepoint

during all scheduled visits

Method of measurement

Assessment of the adverse events

Secondary outcomes

1

Description

Subject satisfaction

Timepoint

Day 14, Day 120

Method of measurement

Likert satisfaction scale

2

Description

The need for touch-up injections

Timepoint

Day 14

Method of measurement

Physcian assessment

3

Description

Total injected dose

Timepoint

Day 14

Method of measurement

Calculating total injected dose

4

Description

The onset of action

Timepoint

Day 14

Method of measurement

Subject self assessment (SSA)

Intervention groups

1

Description
Intervention group: Injection of Botulinum Toxin Type A (Lucentra®) manufactured by Espad Pharmed Co, supplied in 300- and 500-unit vials.The intervention consists of a single-session injection into the upper facial area.(The dose and injection sites are determined based on the participant’s needs and the physician’s routine practice.)Touch-up injection on day 14 is permitted at the investigator’s discretion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr. Amir Hooshang Ehsani

Street address
Vahdat Eslami Street, Vahdat Eslami sq

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2

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Fateme Saberi

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Recruitment center

Name of recruitment center
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Full name of responsible person
Mahshid sadat Ansari

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Mahshid.ansarii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Espad Pharmed

Full name of responsible person
Dr. Hooshiar Gholami

Street address
No. 56, Azimi Street, Nafisi Street, Ekbatan

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1393833166

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info@espadpharmedco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Espad Pharmed

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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Orchid Pharmed Co

Full name of responsible person

Dr. Hamid reza Kafi

Position
Medical Department Mnager

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No 42. Attar sq, Attar st, Valiasr st,Vanak sq, Tehram, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Science

Full name of responsible person
Dr. Amir Hooshang Ehsani

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for updating data

Contact

Name of organization / entity
Orchid Pharmed Co

Full name of responsible person
Dr. Hamid reza Kafi

Position
Medical Department Mnager

Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable