

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluating the Safety and Efficacy of highly viscous 33mg/ml Hyaluronic Acid volumiting filler in the treatment of facial wrinkles

Protocol summary

Study aim

Evaluating the Safety and Efficacy of highly viscous 33mg/ml Hyaluronic Acid volumiting filler in the Treatment of Facial Wrinkles

Design

Quasi-experimental clinical trial without control group

Settings and conduct

Azad University hospitals Tehran Medical Branch

Participants/Inclusion and exclusion criteria

Inclusion Criteria :Facial Wrinkles;Exclusion Criteria :Use of other Treatment in past 3 months

Intervention groups

Patients with Facial Wrinkles

Main outcome variables

Score of Before Treatment ; score of 6 months after Treatment ; Score of 12 months after Treatment

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Email address

s_tehrani@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Evaluating the Safety and Efficacy of highly viscous 33mg/ml Hyaluronic Acid volumiting filler in the treatment of facial wrinkles

Public title

Effect of Hyaluronic Acid in Wrinkles Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Facial Wrinkles

Exclusion criteria:

Use of other treatments in past 3 months Patients with Neuromuscular junction disorder Active Infection near the site of Injection Allergy or Hypersensitivity to Hyaluronic Acid

Age

No age limit

Gender

Both

Phase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180228038905N1**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Setareh Tehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

Groups that have been masked

No information

Sample size

Target sample size: 86

Actual sample size reached: 86

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 Islamic Azad University of
Medical Sciences Tehran branch**Street address**

Islamic Azad University , Khaghani St., Shariati St.

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.IAU.TMU.REC.1396.121

Health conditions studied**1****Description of health condition studied**

Facial Wrinkles

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Score of Facial Wrinkles

Timepoint

Before injection , 6 & 12 months after injection

Method of measurement

Inspection

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The product we used in this study was Variofil with the concentration of 33 mg/ml Hyaluronic Acid , The intensity of Facial Wrinkles determined the usage dose , we injected single dose & 2 weeks after injection if it was necessary , It is Injectable Filler , This Filler is product by a German company ADODERM GmbH

Category

Treatment - Other

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

Amiralmomenin hospital

Full name of responsible person

Setareh Tehrani

Street addressAmiralmomenin Hospital, Shir Mohammadi St., Nazi
Abad Town**City**

Tehran

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Postal code

193951495

Phone

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Email

info@amhos.ir

2**Recruitment center****Name of recruitment center**

Qods clinic

Full name of responsible person

Setareh Tehrani

Street address

Ghods Clinic, Ivanaki Ave., sixth phase, Qods Town

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3

Recruitment center

Name of recruitment center

Javaheri Hospital

Full name of responsible person

Setareh Tehrani

Street address

Javaheri Hospital, Khaghani St., shariati St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Nadia Sharifi

Street address

Islamic Azad University Medical Sciences Branch,
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iautmu@iautmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Setareh Tehrani

Position

Assistant proffessor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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s_tehrani@iautmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Setare Tehrani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Email

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

We share only part of information include of concentration of drug that is use, site of injection , efficacy, and side effects

When the data will become available and for how long

One year after publication

To whom data/document is available

Researchers of Universities and scientific institutes

Under which criteria data/document could be used

In order to improve current treatment procedure

From where data/document is obtainable

Contact with corespondent: Dr Setareh Tehrani email: s_tehrani@iautmu.ac.ir tel: 00982122006660 Address: Islamic Azad University Medical Science Branch, Khaghani St., Shariati St, Tehran Postal Code: 193951495

What processes are involved for a request to access data/document

Send written request to corespondent email. It takes almost two weeks to respond

Comments