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

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
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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

2

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 address

Amiralmomenin Hospital, Shir Mohammadi St., Nazi Abad Town

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2

Recruitment center

Name of recruitment center

Qods clinic

Full name of responsible person

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3

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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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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 iclude 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