Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of efficacy of " Botulinium Toxin A plus Triamcinolone" intralesional injection with intralesional injection of Triamcinolone alone for treatment of keloid

Protocol summary

Summary

The goal of this study is the comparison of Botolinium toxin A plus triamcinolon with triamcinolone alone for treatment of keloid.This study is single blined.Patients should have at least two keloids and they should not be pregnant or breast feeding.Sample size is 20 patients.Two distinct lesions will go under one of theese treatments(after general anesthesia):1-Intralesional injection of triamcinolon 2-Intralesional injection of triamcinolone+BTA.Treatment will be contineud monthly for 3 monthes.At each treatment session the height,consistency,pigmentation and vascularisation of keloids will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071918533N1**
Registration date: **2014-08-11, 1393/05/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-11, 1393/05/20

Registrant information

Name

Nasibe Sohrabian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 661 3067

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Recruitment status

Recruitment complete

Funding source

neuronox company

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of " Botulinium Toxin A plus Triamcinolone" intralesional injection with intralesional injection of Triamcinolone alone for treatment of keloid

Public title

Assessment of efficacy of Botulinium toxin A for treatment of keloid

Purpose

Treatment

Inclusion/Exclusion criteria

]nclusion criteria:patients should have at least too keloids on the skin ;age between 15 and 45 years Exclusion criteria:pregnant or breast feeding women ;neuromuscular jaunction diseases or receiving neuromuscular junction blocker agents

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University, Daneshgah Sq, Ahvaz, Iran

City

Ahvaz

Postal code

61357-15794

Approval date

2014-04-09, 1393/01/20

Ethics committee reference number

ajums.REC.1393.143

Health conditions studied

1

Description of health condition studied

keloid scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Height of keloid

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Caliper in milimeters

2

Description

Consistency of keloid

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Physical examination score 1-5

3

Description

Vascularity

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Physical examination score 1-3

4

Description

Pigmentation

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Physical examination score 1-3

5

Description

Pain

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Subjective scale of pain:score 1-10

6

Description

Itch

Timepoint

Before treatment ond 1 month after end of treatment

Method of measurement

Subjective scale of itch:score 1-10

Secondary outcomes

1

Description

skin atrophy

Timepoint

1 month after end of treatment

Method of measurement

yes or no

Intervention groups

1

Description

Triamcinolone intralesional injection 20mg/ml monthly for 3 months

Category
Treatment - Drugs

2

Description
Triamcinolone intralesional injection 20mg/ml+Botulinum toxin A 20u/ml intralesional injection monthly for 3months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital of Ahvaz
Full name of responsible person
Dr Sima Rasaii
Street address
Dermatology department of Imam Khomeini hospital, Azdegan Av, Ahvaz, Iran
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neuronox company(Tehran reseller)
Full name of responsible person
Dr Masoud Saghafi
Street address
No34, Aftab St, Khoddami St, Vanak Sq, Tehran, IRAN
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neuronox company(Tehran reseller)
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty