

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 Botulinium toxin A plus triamcinolon with triamcinolone alone for treatment of keloid. This study is single blinded. 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 these treatments (after general anesthesia): 1- Intralesional injection of triamcinolon 2- Intralesional injection of triamcinolone+BTA. Treatment will be continued monthly for 3 months. 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

Inclusion criteria: patients should have at least two keloids on the skin ; age between 15 and 45 years

Exclusion criteria: pregnant or breast feeding women ; neuromuscular junction 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 and 1 month after end of treatment

Method of measurement

Caliper in millimeters

2

Description

Consistency of keloid

Timepoint

Before treatment and 1 month after end of treatment

Method of measurement

Physical examination score 1-5

3

Description

Vascularity

Timepoint

Before treatment and 1 month after end of treatment

Method of measurement

Physical examination score 1-3

4

Description

Pigmentation

Timepoint

Before treatment and 1 month after end of treatment

Method of measurement

Physical examination score 1-3

5

Description

Pain

Timepoint

Before treatment and 1 month after end of treatment

Method of measurement

Subjective scale of pain:score 1-10

6

Description

Itch

Timepoint

Before treatment and 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Neuronox company(Tehran reseller)

Full name of responsible person

Dr Masoud Saghafi

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No34, Aftab St, Khoddami St, Vanak Sq, Tehran, IRAN

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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****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Resident of Dermatology

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Web page address

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