

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Botulinum toxin type A effects on the treatment of keloid lesions; Comparison of intralesional two different doses

#### Protocol summary

##### Summary

Objectives: Keloid is a lesion that creates from the excessive restoration of the scar and has beauty and functional complications for patient and changes their quality of life. Today, varieties of methods are used but because of lesion recurrence, patients' problems last. In this study, the two different doses of botulinum toxin type A, impact on the treatment of keloid lesion has been investigated. Design: In this double blind clinical trial, (phase 3), 43 patients with keloid lesions were interfered. Patients were randomly assigned to one of two groups. The lesion was randomly divided into two portions in each patient. Setting and conduct: Randomization based on quaternary numbers blocking was done by computer software. Participants including major eligibility criteria: Inclusion criteria: patients with keloid, age between 12-65 years, patients consent to participate in the study with knowledge of the conditions and its implications. Exclusion criteria: sensitivity to BTX-A, pregnant and breastfeeding women Intervention: Each patient receives botulinum toxin type A with concentration 200 units per ml with the dose of 10 or 20 units per cubic centimeter lesion in a part of the lesion. In another part of the lesion, normal saline was injected with the same volume. Injections have been done monthly to three times. Patients were evaluated 9 months after the last injection, according to the Vancouver scar scales and Results were analyzed in both groups. Main outcome measures: according to the Vancouver scar scales: pigmentation, vascularity, height, and pliability.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020926489N1**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-15, 1395/08/25

##### Registrant information

###### Name

Ahmad Reza Taheri

###### Name of organization / entity

School of Medicine, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2478

###### Email address

taheriah@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

There is no funding source

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-12-01, 1394/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Botulinum toxin type A effects on the treatment of keloid lesions; Comparison of intralesional two different doses

##### Public title

The effect of botox in treatment of scar

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients with keloid lesion greater 2cm; patient age between 12-65 years of old; patients consent to participate in the study; Exclusion criteria: patients with keloid lesion smaller than 1.9cm; lack of patient satisfaction in doing a research intervention; sensitivity to BTX-A; pregnant and breastfeeding women; patients with neuromuscular diseases.

## Age

From **12 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **86**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

School of Medicine, Tehran University of Medical Sciences, IR.TUMS.REC

##### Street address

Keshavarz Blvd., Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2015-11-10, 1394/08/19

#### Ethics committee reference number

IR.TUMS.REC.1394.1138

## Health conditions studied

### 1

#### Description of health condition studied

Keloid Lesion

#### ICD-10 code

L91.0

## ICD-10 code description

Diseases of skin and soft tissue

## Primary outcomes

### 1

#### Description

Pigmentation

#### Timepoint

0-9monthes after last intervention

#### Method of measurement

By observers

### 2

#### Description

Vascularity

#### Timepoint

At beginig and 9th monthes after last injection

#### Method of measurement

By observers

### 3

#### Description

Height

#### Timepoint

At beginig and 9th monthes after last injection

#### Method of measurement

By observers

### 4

#### Description

Pliability

#### Timepoint

At beginig and 9th monthes after last injection

#### Method of measurement

By observers

## Secondary outcomes

### 1

#### Description

Peri-lesional atrophy

#### Timepoint

At the begining of the study and 9 monthes after last injection

#### Method of measurement

assessment by ruler

## Intervention groups

### 1

#### Description

Each patient receives botulinum toxin type A with concentration 200 units per ml with the dose of 10 or 20 units per cubic centimeter lesion in a part of the lesion. In another part of the lesion, normal saline was injected

with the same volume. Injections have been done monthly to three times. Patients were evaluated 9 months after the last injection, according to the Vancouver scar scales and Results were analyzed in both groups.

**Category**

Treatment - Drugs

**2**

**Description**

In group two of intervention, each lesion receives botulinum toxin type A with concentration 200 units per ml with the dose of 20 units per cubic centimeter lesion in a part of the lesion. Injections have been done monthly to three times.

**Category**

Treatment - Drugs

**3**

**Description**

In the first control group, another part of the lesion, receives normal saline with the same volume of botulinum toxin type A was injected in group one. Injections have been done monthly to three times and synchronous with the toxin.

**Category**

Treatment - Drugs

**4**

**Description**

In the second control group, another part of the lesion, receives normal saline with the same volume of botulinum toxin type A was injected in group two. Injections have been done monthly to three times and synchronous with the toxin.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Plastic surgery clinic, Imam khomeini hospital

**Full name of responsible person**

Dr. Afshin Fathi

**Street address**

Plastic surgery clinic, Imam Khomeini hospital, Keshavarz blvd.

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

School of Medicine, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Kaviani

**Street address**

School of Medicine, Tehran University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

School of Medicine, Tehran University of Medical Sciences

**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**

School of Medicine, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Fathi

**Position**

Plastic Surgeon

**Other areas of specialty/work**

**Street address**

Department of Plastic and Reconstructive surgery, Imam Khomeini hospital, Keshavarz Blvd.

**City**

Tehran

**Postal code**

00982161192472

**Phone**

+98 21 6119 2472

**Fax**

+98 21 6119 2472

**Email**

dr.fathi110@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

School of Medicine, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Ahmad Reza Taheri

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Department of Plastic and Reconstructive surgery,  
Imam Khomeini Hospital, Keshavarz Blvd.

**City**

Tehran

**Postal code****Phone**

+98 21 6119 2478

**Fax****Email**

taheriah@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

School of Medicine

**Full name of responsible person**

Dr. Afshin Fathi

**Position**

Plastic Surgeon

**Other areas of specialty/work****Street address**

Department of Plastic and Reconstructive surgery,  
Imam Khomeini hospital, Keshavarz Blvd.

**City**

Tehran

**Postal code****Phone**

+98 21 6119 2472

**Fax****Email**

dr.fathi110@yahoo.com

**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*