

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of botulinum toxin A on preventing of abdominoplasty and mamoplasty surgery scar

Protocol summary

Study aim

Evaluation of the effect of botulinum toxin A on preventing of abdominoplasty and mamoplasty surgery scar

Design

On twenty patients 2 weeks after operation Botox and normal saline will be injected at two different side of the scar. Clinical trial has control group in study phase 3

Settings and conduct

In Razi hospital injection will be done by dermatologist who doesn't know the kind of syringe (Botox or normal saline)

Participants/Inclusion and exclusion criteria

Patients with mammoplasty and abdominoplasty scar, operated during past 10 days

Intervention groups

two weeks after surgery Botox will be injected at one side and normal saline at the other side

Main outcome variables

modified Stony Brook Scar Evaluation Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040876N1**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Neda Mehdizade rayeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 3760

Email address

nedashervin95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of botulinum toxin A on preventing of abdominoplasty and mamoplasty surgery scar

Public title

Evaluation of botulinum toxin on preventing of scar

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mammoplasty and abdominoplasty scar, operated during past 10 days

Exclusion criteria:

Allergy to botox Pregnancy and breastfeeding History of radiotherapy and chemotherapy Neuromotor diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Injection in right or left side of the scar

Randomization (investigator's opinion)

Randomized

Randomization description

Right or left side of the scar will be injected randomly

Blinding (investigator's opinion)

Double blinded

Blinding description

Dermatologist who doesn't know syringe kind(Botox or normal saline) will inject it to the right or left

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Tehran University of Medical Sciences

Street address

Tehran university of medical sciences,ghods street,keshavarz bolvar

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.068

Health conditions studied

1

Description of health condition studied

scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

modified Stony Brook Scar Evaluation Scale

Timepoint

3&6 month after injection

Method of measurement

Including 4 factors: width, height, scar color and incision line. scoring is based on 0-8

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: two weeks after surgery Botox will be injected at one side and normal saline at the other side

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Neda mehdizade

Street address

razi hospital,vahdat eslami st,tehran

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tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0853

Email

razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohmad jafar sadigh damghani zade

Street address

16th Azar St., Enghelab Sq., Tehran, Iran

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+98 21 6111 3411

Email

Publicrel@ut.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Neda mehdizade rayeni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

neda mehdizade rayeni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Resient

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available