Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of botolinum 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
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Iran (Islamic Republic of)
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+98 21 2209 3760
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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 botolinum toxin A on preventing of abdominoplasty and mamoplasty surgery scar

Public title
Evaluation of botolinum 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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1199663911
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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
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16th Azar St., Enghelab Sq., Tehran, Iran
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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
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Position
Resident
Latest degree
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Person responsible for updating data

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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