

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effect of topical tetracycline and placebo on the frequency of seroma formation after abdominoplasty

Protocol summary

Study aim

Comparison of the effect of topical tetracycline and placebo on the frequency of seroma formation after abdominoplasty

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 100 patients undergoing abdominoplasty

Settings and conduct

This study will be conducted with the aim of comparison of the effect of topical tetracycline and placebo on the frequency of seroma formation after abdominoplasty on 100 patients attending Ali Ebne Abitaleb hospital in Zahedan city. After inclusion in the study, the patients will be assigned into two groups; tetracycline group and placebo group. In tetracycline group, powder of 10 tetracycline capsules is dissolved in 50 ml of normal saline and injected at the surgery site and in the placebo group 50 ml of normal saline is injected at the surgery site. 7 and 30 days after the surgery the patients are examined for seroma formation and the two groups will be compared together.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 35 to 55; body mass index of 30 to 40 kg/m². Exclusion criteria: having drug addiction; having underlying diseases such as cardiac, renal or liver diseases.

Intervention groups

Intervention group: powder of 10 tetracycline capsules is dissolved in 50 ml of normal saline and injected at the surgery site Control group: 50 ml of normal saline is injected at the surgery site

Main outcome variables

Seroma formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210224050489N1**

Registration date: **2021-04-03, 1400/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-03, 1400/01/14**

Update count: **0**

Registration date

2021-04-03, 1400/01/14

Registrant information

Name

Hamidreza Jami Mohareri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

mohareri@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of topical tetracycline and placebo on the frequency of seroma formation after abdominoplasty

Public title

Comparison of the effect of topical tetracycline and placebo on the frequency of seroma formation after abdominoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 35 to 55 Body mass index of 30 to 40 kg/m²

Exclusion criteria:

Having drug addiction Having underlying diseases such as cardiac, renal or liver diseases

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly assigned into two groups (tetracycline and placebo) using a random number table. A random number table containing unrepeated numbers between 1 and 100 is selected and the reading is started from the left. If the number is odd the patient is assigned into tetracycline group and if the number is even the patient is assigned into placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and person evaluating the patients are not aware of patients assignment and so are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.ZAUMS.REC.1399.505

Health conditions studied

1

Description of health condition studied

Abdominoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Seroma formation

Timepoint

7 and 30 days after the surgery

Method of measurement

By inspecting the surgery site

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: powder of 10 tetracycline capsules is dissolved in 50 ml of normal saline and injected at the surgery site

Category

Prevention

2

Description

Control group: 50 ml of normal saline is injected at the surgery site

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Hamidreza Jami Mohareri
Street address
Khalije Fars Blv, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
ayubabedi48@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of
Medical Sciences, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5721
Email
Dr.Taheri@zaums.ac.ir
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Hamidreza Jami Mohareri

Position
General surgery specialist
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Ali Ebne Abi Taleb Hospital ,Khalije Fars Blv, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Fax
Email
mohareri@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hamidreza Jami Mohareri
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Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Fax
Email
mohareri@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hamidreza Jami Mohareri
Position
General surgery specialist
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Specialist
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General Surgery
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9916789547

Phone

+98 54 3329 5715

Fax

Email

mohareri@zaums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable