

# 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/m<sup>2</sup>. 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/m<sup>2</sup>

### 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  
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Zahedan  
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**Phone**  
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**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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General surgery specialist  
**Latest degree**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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**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