

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparing Z-plasty versus Z-plasty and skin grafting for surgical tension free treatment of post-burn elbow contractures: A randomized clinical trial

#### Protocol summary

##### Summary

Objectives: Comparing Z-plasty versus Z-plasty and skin grafting in surgical tension free treatment of post-burn elbow contractures. Design: Thirty patients with 15 to 60 degrees elbow joint extension restriction are going to participate in this study in two groups. Setting and conduct: a hospital in Zanzan city, Iran, from March 2013. Inclusion criteria: Having un-circumferential scar (circumferential until 75%); 15 to 60 degrees flexion and extension restriction in elbow joint; no joint ossification. Exclusion criteria: having comorbid diseases; joint ossification; wound infection; underlying medical illnesses such as diabetes, uremia, hypertension, cardiovascular diseases, chronic arterial obstruction, immunodeficiency conditions and kidney failure; being younger than 15 or older than 60 years old; taking non-steroidal anti-inflammatory drugs; high dosage of corticosteroids or chemotherapy agents. Intervention: In both groups Z-plasty is designed with a 60 degrees angle. But in the investigation group the flaps will be turned without tension. Then the upper and lower of the flaps will be grafted by mid split-thickness skin graft. Outcome measures: The surgery area will be examined regarding infections, wound healing time, necrosis and scar. Significant differences will be evaluated using unpaired student T-test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201611235560N1**

Registration date: **2017-01-03, 1395/10/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-03, 1395/10/14

##### Registrant information

###### Name

Seyed Nejat Hosseini

###### Name of organization / entity

Zanzan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24009833440300

###### Email address

nejat.hosini@zums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2013-02-19, 1391/12/01

##### Expected recruitment end date

2016-12-19, 1395/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing Z-plasty versus Z-plasty and skin grafting for surgical tension free treatment of post-burn elbow contractures: A randomized clinical trial

##### Public title

Comparing Z-plasty versus Z-plasty and skin grafting for surgical tension free treatment of post-burn elbow contractures

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Having un-circumferential scar (circumferential until 75%); 15 to 60 degrees flexion and extension restriction in elbow joint; no joint ossification. Exclusion criteria: having comorbid diseases; joint ossification; wound infection; underlying medical illnesses such as diabetes, uremia, hypertension, cardiovascular diseases, chronic arterial obstruction, immunodeficiency conditions and kidney failure; being younger than 15 or older than 60 years old; taking non-steroidal anti-inflammatory drugs; high dosage of corticosteroids or chemotherapy agents.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Sealed envelope

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

##### Street address

Mahdavi Blvd

##### City

Zanjan

##### Postal code

#### Approval date

2013-09-23, 1392/07/01

#### Ethics committee reference number

zums.rec.1392.118

## Health conditions studied

### 1

#### Description of health condition studied

Elbow contracture

#### ICD-10 code

T22.0

#### ICD-10 code description

Burn of unspecified degree of shoulder and upper limb, except wrist and hand

## Primary outcomes

### 1

#### Description

Infection

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

#### Method of measurement

Examination

### 2

#### Description

Wound healing time

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

#### Method of measurement

Examination

### 3

#### Description

Scar depth

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

#### Method of measurement

Examination

### 4

#### Description

Contracture details

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

#### Method of measurement

Examination

### 5

#### Description

Necrosis

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

#### Method of measurement

Examination

### 6

#### Description

New scar

#### Timepoint

2nd, 4th, 8th, 12th, 24th weeks after the surgery

**Method of measurement**

Examination

7**Description**

Motion range of the joint

**Timepoint**

2nd, 4th, 8th, 12th, 24th weeks after the surgery

**Method of measurement**

Examination

**Secondary outcomes**

empty

**Intervention groups**1**Description**

The investigation group will be treated with Z-plasty and skin graft.

**Category**

Treatment - Surgery

2**Description**

The control group will be treated with Z-plasty without skin graft.

**Category**

Treatment - Surgery

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Ayatollah Mousavi Hospital

**Full name of responsible person**

Seyed Nejat Hosseini

**Street address**

Gavazang Blvd

**City**

Zanjan

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Vice chancellor for research of Zanjan University of Medical Sciences

**Full name of responsible person**

Alireza Shoghli (vice chancellor for research)

**Street address**

Mahdavi Blvd

**City**

Zanjan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Seyed Nejat Hosseini

**Position**

Plastic Surgeon and Academic Member

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

Faculty of Medicine, Mahdavi Blvd

**City**

Zanjan

**Postal code**

4513956111

**Phone**

00

**Fax****Email**

nejat.hosini@zums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Seyed Nejat Hosseini

**Position**

Plastic and Aesthetic Surgery

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

Faculty of Medicine, Mahdavi Blvd

**City**

Zanjan

**Postal code**

4513956111

**Phone**

+98 24 3344 0300

**Fax**  
**Email** nejat.hosini@zums.ac.ir  
**Web page address**

+98 24 3344 0300  
**Fax**  
**Email**  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Seyed Nejat Hosseini  
**Position**  
Plastic and Aesthetic Surgery  
**Other areas of specialty/work**  
**Street address**  
Faculty of Medicine, End of Mahdavi Blvd  
**City**  
Zanjan  
**Postal code**  
**Phone**

## 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*