Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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 Zanjan 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

Zanjan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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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 committe 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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