Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between treatment outcomes of soft tissue distraction in addition to Z-plasty and Z-plasty alone after skin graft in patients with chronic flexion contracture of interphalangeal joints due to previous traumatic abrasive injuries

Protocol summary

Summary

Aim: Interphalangeal (IP) joint contracture is a common and challenging complication of hand trauma. Several techniques for soft tissue distraction has been developed during the past few decades. Pentagonal frame is the latest technique that was introduced in 2009 as effective method for treatment of flexion contractures of hand. Study population: In this study, patients with chronic flexion contracture of interphalangeal joints following trauma will be treated using two surgical techniques in two groups each containing 20 patients. Major inclusion and exclusion criteria: Patients with long-standing scars on fingers for more than 6 months after the trauma with a history of unsuccessful medical treatment for the past 6 months will be evaluated. Patients with history of muscular or bone injuries of the fingers, acute inflammation, sensory, motor or vascular problem within the hand will be excluded. Intervention: In the first group soft tissue distraction using pentagonal frame following scar release using Z-plasty in the treatment of post-traumatic long-standing flexion contracture of proximal and distal interphalangeal joints and in the second group multiple Z-plasties alone will be done alone. Primary outcomes: after surgical intervention, flexion contracture and range of motion in interphalangeal joints will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201298861N1**
Registration date: **2012-03-15, 1390/12/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-03-15, 1390/12/25

Registrant information

Name
Mohammad Reza Keramati
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6658 1657
Email address
mr-keramati@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2011-08-01, 1390/05/10

Expected recruitment end date

2012-02-01, 1390/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between treatment outcomes of soft tissue distraction in addition to Z-plasty and Z-plasty alone after skin graft in patients with chronic flexion contracture of interphalangeal joints due to previous traumatic abrasive injuries

Public title
Soft tissue distraction using pentagonal frame in long standing traumatic flexion deformity of interphalangeal joints
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with long-standing scars on fingers for more than 6 months after the trauma with a history of unsuccessful medical treatment for the past 6 months. Exclusion criteria: history of muscular and/or bone injuries of the fingers (only pure cutaneous and subcutaneous traumatic injuries resulting scar formation will be studied); Bone fracture (using X-rays); acute inflammation or granulation tissue; History of other medical comorbidities including medical or surgical problems, immune-suppression; previous history of surgery in the involved hand; any previous traumatic injuries of the hand; physical exam revealing any sensory, motor or vascular problem within the hand.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran university of medical sciences
Street address
6th floor, Central building of Tehran university of medical sciences, Ghods St., Keshavarz Ave.
City
Tehran
Postal code
Approval date
2011-08-01, 1390/05/10
Ethics committee reference number
695/130/90/د

Health conditions studied

1

Description of health condition studied
Flexion contracture of proximal and distal interphalangeal finger joints
ICD-10 code
M20.0
ICD-10 code description
Deformity of finger(s)

Primary outcomes

1

Description
Degree of flexion contracture of proximal interphalangeal finger joints
Timepoint
before surgery, six months after surgery
Method of measurement
Degree using measure

2

Description
Degree of flexion contracture of distal interphalangeal finger joints
Timepoint
before surgery, six months after surgery
Method of measurement
Degree using measure

Secondary outcomes

1

Description
Range of motion of proximal interphalangeal finger joint
Timepoint
before surgery, six months after surgery
Method of measurement
degree using measure

2

Description
Range of motion of distal interphalangeal finger joint
Timepoint
before surgery, six months after surgery
Method of measurement
degree using measure

Intervention groups

1

Description

Group A (intervention) : Soft tissue distraction will be performed using pentagonal frame technique. In this method, primarily, scars and contractures will be released using single or multiple Z or zigzag incisions for lengthening. A Kirschner wire size 1–1.5 mm (matching the patient’s distal phalanx thickness) will be used for anchorage. The wire wll be passed horizontally, under direct fluoroscopic control, through the head of the phalanx and then bent like a pentagon. Before closing the wire ends, a rubber band will be inserted inside the frame. The frame will be shaped such that only the horizontal wire segment exerts the ‘‘distraction,’’ and no vascular compromise or soft tissue encroachment will be created. An external fixation device will then be used to distract the finger.

Category

Treatment - Surgery

2

Description

Group B (Control) : In this group, scars and contracture will be release using single or multiple Z or zigzag incisions for lengthening. Then, a splint will be used to hold the finger in full extension position.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran university of medical sciences, Firoozgar hospital

Full name of responsible person

Dr. Mohammad Reza Keramati

Street address

Behafarin St, Karimkhan Ave, Valie-asr Sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Researach deputy of Tehran university of medical sciences, Faculty of medicine

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

Faculty of medicine, Poor-sina St, Shanzdah-azar St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Researach deputy of Tehran university of medical sciences, Faculty of medicine

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

Tehran university of medical sciences

Full name of responsible person

Dr. Mohammad Reza Keramati

Position

Resident of surgery

Other areas of specialty/work

Street address

Apt.43, No.32, Parastoo St., Kamraniye Ave.

City

Tehran

Postal code

1951955531

Phone

+98 21 2283 3381

Fax

Email

mr-keramati@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Mohammad Reza Keramati

Position

Resident of surgery

Other areas of specialty/work

Street address

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City

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Phone

+98 21 2283 3381

Fax

Email

mr-keramati@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran university of medical sciences

Full name of responsible person
Dr. Mohammad Reza Keramati

Position
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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