

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Randomized clinical trial comparing surgical and aesthetic outcomes following endoscopic-assisted tissue neck expansion and open approach in reconstruction of major facial burn injuries

Protocol summary

Summary

Objective: Recently endoscopy has shown promises in reconstructive surgeries using tissue expander placement. This study aims to compare outcomes between open and endoscopic-assisted neck tissue expander placement in reconstruction of post-burn facial scar deformity. Design: Through a randomized clinical trial, patients with facial burn scar were assigned to either open group and endoscopic group undergoing placement of tissue expanders. Setting and conduct: Department of Plastic and Reconstructive Surgery, Saint Fatima Hospital, Iran University of Medical Sciences, Tehran, Iran Participants including major eligibility criteria: Patients with major facial burn injuries requiring tissue expansion reconstruction will be included. Patients with immunocompromised status, extending burn to the neck region and inability to participate will be excluded. Intervention: Tissue expanders are placed in neck through endoscopic approach in Intervention group and through open technique in Control group main outcome measures variable: Complication rate, operative time, length of hospital stay and time to full expansion

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307319044N2**
Registration date: **2013-12-11, 1392/09/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-11, 1392/09/20

Registrant information

Name

Kamran Asadi

Name of organization / entity

Tehran University of Medical Sciences, Motahari Burn Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 6226

Email address

asadi_kamran@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-10-01, 1392/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial comparing surgical and aesthetic outcomes following endoscopic-assisted tissue neck expansion and open approach in reconstruction of major facial burn injuries

Public title

Reconstruction of major extensive facial burn injuries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Major facial burn injuries requiring

tissue expansion reconstruction Exclusion Criteria:
Immuno-compromised status; extending burn to the neck region; inability to participate in the study

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Ethics Committee/ Iran University of Medical Sciences

Street address

Saint Fatemeh Hospital, Yousef Abad

City

Tehran

Postal code

1433933111

Approval date

2013-10-10, 1392/07/18

Ethics committee reference number

92-10-10-13509-478321

Health conditions studied

1

Description of health condition studied

Facial Burn

ICD-10 code

T20, T21,

ICD-10 code description

Burns and corrosions

Primary outcomes

1

Description

Operative time

Timepoint

During the Surgery

Method of measurement

Timer

2

Description

Hospital stay

Timepoint

During Hospitalization

Method of measurement

Calendar

3

Description

Time to Full Expansion

Timepoint

After the Surgery

Method of measurement

Calendar

Secondary outcomes

1

Description

Complications

Timepoint

Intra-operative and post-operative

Method of measurement

Examination and History Taking

Intervention groups

1

Description

Intervention group Using an endoscopic approach, tissue expanders are placed in neck pocket tissue and connected to a port far away at the port site. Following achievement of full expansion of neck tissue, flaps are removed from expansion site and used for reconstruction of facial burn.

Category

Treatment - Surgery

2

Description

Control group In this group, the traditional open approach is used to insert tissue expander and connected to the port near its location. After full expansion, tissues are removed and transferred to cover the facial burn scar deformities.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Plastic and Reconstructive Surgery/
Saint Fatima Hospital

Full name of responsible person

Kamran As'adi

Street address

Suite 2, Afra Tower, Khashayar Park, Africa Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of
Medical Sciences

Full name of responsible person

Dr Morteza Nobakht

Street address

Hemmat Highway, Between Chamran and Sheikh
Fazlollah, Iran University of Medical Sciences, Central
Building, 5th Floor

City

Tehran

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, Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Kamran As'adi

Position

Assistant Professor

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

Suite 2, Afra Tower, Khashayar Park, Africa Blvd

City

Tehran

Postal code

1915683913

Phone

+98 21 8887 6226

Fax**Email**

dr.kamran.asadi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Kamran As'adi

Position

Assistant Professor

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

Suite 2, Afra Tower, Khashayar Park, Africa Blvd

City

Tehran

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+98 21 8887 6226

Fax**Email**

dr.kamran.asadi@gmail.com

Web page address

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