

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Efficacy of custom made appliance by method of CAD/CAM compared with conventional dressing for reducing facial swelling after maxillofacial surgery

Protocol summary

Summary

The purpose of this study was to investigate the effect of custom made appliance by method of CAD/CAM compared with conventional dressing for reducing facial swelling after maxillofacial surgery. This study was accomplished on 14 patients referred to department oral and maxillofacial surgery at Bahonar hospital in Kerman. Inclusion criteria: patients who have similar bilateral fractures of the upper or lower of jaw; Patients who need orthognathic surgery for similar osteotomy upper or lower jaw. Exclusion criteria: Patients who have asymmetry in their examination; Patient who has a previous history of oral and maxillofacial surgery; Patients with systemic diseases such as diabetes mellitus affecting the healing process and swelling. CT scan of patients was taken to build of custom made appliance. Based on three-dimensional reconstruction custom made appliance was designed and built. Swelling measured before surgery, immediately after surgery, 24 hours, 48 hours and 7 days later. Primary outcome measure was swelling. Secondary outcome measure was type of surgery. Intervention includes type of surgery and type of compression bandage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040427214N1**
Registration date: **2016-04-22, 1395/02/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-22, 1395/02/03

Registrant information

Name

Mohsen Barzegar

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3121 5600

Email address

m.barzegar@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Abbas Pardakhti

Expected recruitment start date

2014-09-11, 1393/06/20

Expected recruitment end date

2015-07-11, 1394/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of custom made appliance by method of CAD/CAM compared with conventional dressing for reducing facial swelling after maxillofacial surgery

Public title

Efficacy of custom made tool for reducing facial swelling after maxillofacial surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who have similar bilateral

fractures of the upper or lower of jaw; Patients who need surgery for incising soft tissue similar in both sides; Patients who need orthognathic surgery for similar osteotomy upper or lower jaw Exclusion criteria: Patients who have asymmetry in their examination; Patient who has a previous history of oral and maxillofacial surgery; Patient who has severe damage and unusual soft tissue swelling after trauma; Patients with systemic diseases such as diabetes mellitus affecting the healing process and swelling; Patients who do not have cooperation during the study

Age

From **19 years** old to **33 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Somayeh Crossroads

City

Kerman

Postal code

7618759689

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

k/93/541

Health conditions studied

1

Description of health condition studied

facial fracture

ICD-10 code

S02

ICD-10 code description

Fracture of skull and facial bones

Primary outcomes

1

Description

Swelling

Timepoint

Pre operation time,After surgery,1,2 and 7 days after surgery

Method of measurement

Millimeter

Secondary outcomes

empty

Intervention groups

1

Description

Type of compression bandage: custom made appliance and conventional method Duration 7 days Appliance is fixed on the patient's face

Category

Other

2

Description

Type of surgery: open treatment and internal fixation in similar bilateral facial fractures and orthognathic surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department Oral and Maxillofacial Surgery at Shahid Bahonar hospital in Kerman

Full name of responsible person

Mohsen Barzegar

Street address

Shahid Bahonar hospital, Gharani Avenue

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhti

Street address
Somayeh Crossroad

City
Kerman

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Dental School of Kerman

Full name of responsible person
Mohsen Barzegar

Position
Resident of Oral Maxillofacial Surgery

Other areas of specialty/work

Street address
Shafa Avenue

City
Kerman

Postal code
7618759689

Phone
+98 34332119021

Fax
+98 34 3211 8073

Email
dentistryschool@kmu.ac.ir

Web page address
sd.kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dental School of Kerman

Full name of responsible person
Javad Faryabi

Position

Associate Professor

Other areas of specialty/work

Street address
Shafa Avenue

City
Kerman

Postal code
7618759689

Phone
+98 34332119021

Fax
+98 34 3211 8073

Email
jfomfs@gmail.comdentistryschool@kmu.ac.ir

Web page address
sd.kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Dental School of Kerman

Full name of responsible person
Mohsen Barzegar

Position
Resident Oral Maxillofacial Surgery

Other areas of specialty/work

Street address
Shafa Avenue

City
Kerman

Postal code
7618759689

Phone
+98 34332119021

Fax
+98 34 3211 8073

Email
mohsen.barzegar90@gmail.comdentistryschool@kmu.ac.ir

Web page address
sd.kmu.ac.ir

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