

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the amount of pain, edema and maximum mouth opening before and after the broken zygomatic arch reduction by new method of using fifty mm needle without surgery cut

Protocol summary

Study aim

Comparison of the amount of pain, edema and maximum mouth opening before and after the broken zygomatic arch reduction by new method

Design

Clinical trial; not blinded without control group. Pre and post operative measurement

Settings and conduct

In this research we used a new method: using fifty millimeters needle without surgery cut for replacement of broken zygomatic arch and we compromise the amount of pain, edema, maximum mouth opening and ecchymosis before and after the surgery.

Participants/Inclusion and exclusion criteria

In this situations patients can involved in the study: unilaterally or bilaterally fractures in zygomatic arch; indication for surgery; limitation in moth opening; clinically depression in zygomatic arch in this situations patients should exit from study: multiple fractures in zygomatic arch; other fractures in nasal bone and midfaces; no bone contact; uncontrolled systemic diseases; visiting after 3 weeks

Intervention groups

In all selected patients zygomatic arch reduced with new method of surgery and then the amount of pain, edema and maximum mouth opening before and after the surgery measure

Main outcome variables

Pain; edema and scars after surgery; more opening mouth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047836N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Zahra Dalirakbari azar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 2864

Email address

zahradelirakbari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-27, 1399/04/07

Expected recruitment end date

2020-07-28, 1399/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the amount of pain, edema and maximum mouth opening before and after the broken zygomatic arch reduction by new method of using fifty mm needle without surgery cut

Public title

Comparison of the amount of pain, edema and maximum mouth opening before and after the broken zygomatic arch reduction by new method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilaterally or bilaterally fractures in zygomatic arch

Indication for surgery Limitation in moth opening

Clinically depression in zygomatic arch

Exclusion criteria:

Multiple fractures in zygomatic arch Other fractures in nasal bone and midfaces No bone contact Uncontrolled systemic diseases Visiting after 3 weeks

Age

From **25 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rregional research ethics committee, Tabriz
University of Medical Sciences

Street address

3rd Floor, Central Building, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-06-08, 1399/03/19

Ethics committee reference number

IR.TBZMED.REC.1399.235

Health conditions studied

1

Description of health condition studied

Isolation fracture in zygomatic arch

ICD-10 code

S02.402

ICD-10 code description

Zygomatic fracture

Primary outcomes

1

Description

The amount of pain before and after the surgical procedure of zygomatic arch reduction with a 50 mm needle

Timepoint

Before and immediately after surgery and 1 week later

Method of measurement

Visual Analog Scale (VAS)

2

Description

The amount of edema before and after the broken zygomatic arch reduction by new method of using fifty mm needle without surgery cut

Timepoint

Before and immediately after surgery and 1 week later

Method of measurement

The distance from the tragus to the corner of the eye and the distance from the tragus to the corner of the mouth by the ruler

3

Description

The amount of maximum mouth opening before and after the broken zygomatic arch reduction by new method of using fifty mm needle without surgery cut

Timepoint

Before and immediately after surgery and 1 week later

Method of measurement

Maximum opening without any pressure or pain and Measure the distance between the incisal edge of the upper and lower front teeth with a ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: of all the patients suspected of having a zygomatic arch fracture who referred to Imam Reza Hospital in Tabriz and wish to participate in the

study, as well as with one or more symptoms, including arch-like depression, non-opening of the mouth, pain and tenderness in the arch-like area, After obtaining informed consent, spiral, axial, and coronal CT scans will be received. In the operating room, after anesthesia under Ural intubation, the location of the arch will be determined by touch and marked with a marker. Two 50 mm needles are selected. The first needle is 15 mm in front of the tragus and the second needle is 30 mm in front of the tragus. They enter from the top of the arch and exit the lower part of the arch so that the tip of the needle is at the bottom of the arch and the end of the needle is at the top .The tips and ends of the needles are then removed by four separate needles and pulled out slowly and with gentle to moderate force to determine the touch of the reaction. Then, for external fixation, zero nylon thread is inserted from inside each needle and the needle is removed from the opposite side, and then the needles are removed and the thread along with an abslange will be used as external fixation.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person

Zahra Delirakbari Azar

Street address

in front of the Central Building, Gholghasht Street,

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Tabriz

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zahradelirakbari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samii

Street address

International Relations Office, No 2 Central Building,
Tabriz University of Medical Sciences, University
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Dalirakbari Azar

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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No. 20, Zaferanji alley., Beheshti intersection,. Imam
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Contact

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the main consequences can be shared
**When the data will become available and for how
long**
Start the access period 6 months after printing the
results
To whom data/document is available
Researchers and treatment staff
Under which criteria data/document could be used
For use in studies and treatment of fractures
From where data/document is obtainable
zahra delirakbari azar zahradelirakbari@yahoo.com
**What processes are involved for a request to access
data/document**
Announce personal or organizational details and the
reason for the need for data and how to use it
Comments