

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of ice pack therapy on reduction of sequelae after mandibular third molar surgery

Protocol summary

Summary

The goal of this study is to evaluate the effects of using ice pack on postoperative complications (trismus, edema, pain) of impacted molar surgery. We perform this study on 30 Patients aged 17 to 30 years old with bilateral impacted mandibular third molars. All patients who participate in this study should be healthy without any significant medical problem. The impacted mandibular teeth on both sides should be in nearly the same angulation and position and should have same degree of surgical difficulty on panoramic radiographs. Exclusion criteria include presence of any systemic disease, drug consumption, and pathologic lesion in the third molar area. In each patient, the impacted tooth on one side (study side) is removed with instruction to use ice pack intermittently for 6 hours after surgery. The tooth on the other side (control side) will be removed with no use of postoperative ice pack. The study and control sides and their priority for surgery are randomly selected. The time interval between surgical removal study and control sides should be at least one month. The severity of pain and the degree of edema and trismus were recorded on the second and seventh postoperative days and compared with the baseline preoperative measurements. The examiner who measures the variables is blind to the design and purpose of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410214303N3**
Registration date: **2014-10-23, 1393/08/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-23, 1393/08/01

Registrant information

Name

Mohammad Zandi

Name of organization / entity

Hamedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ice pack therapy on reduction of sequelae after mandibular third molar surgery

Public title

Evaluation of the effect of ice pack therapy on reduction of sequelae after surgery of wisdom tooth in the lower jaw

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy patients with bilateral impacted mandibular third molars. The impacted teeth on both sides should be in nearly same angulation and position and should have same degree of surgical difficulty on panoramic radiographs. Exclusion criteria: Presence of any systemic disease, drug consumption, and pathologic lesion in the third molar area.

Age

From **17 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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, Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh street

City

Hamadan

Postal code

65178

Approval date

2014-10-15, 1393/07/23

Ethics committee reference number

3461/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Postoperative complications

ICD-10 code

K01.1

ICD-10 code description

Embedded teeth

Primary outcomes

1

Description

Trismus

Timepoint

Before surgery, 2 and 7 days after surgery

Method of measurement

Distance between upper and lower central incisal edge

2

Description

Edema

Timepoint

Before surgery, 2 and 7 days after surgery

Method of measurement

Sum of distances from the corner of the mouth to the tragus and from the lateral canthus of the eye to the angle of the mandible

3

Description

Pain

Timepoint

Before surgery, 2 and 7 days after surgery

Method of measurement

Four-point scale (0, no pain; 1, mild pain; 2, moderate pain; 3, severe pain)

Secondary outcomes

empty

Intervention groups

1

Description

Ice pack therapy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zandi

Street address

Department of oral and maxillofacial surgery, Faculty of Dentistry, Shahid Fahmideh street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Bashirian, Vice- Chancellor of university in research affairs

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh street

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Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Faculty of Dentistry, Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zandi

Position

Associate Professor of Oral and Maxillofacial surgery

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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