Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 Committeeو 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

City
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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
City
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
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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