

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

effect of an oily calcium hydroxide suspension on pain and complications after surgical removal of impacted third molar

Protocol summary

2014-04-17, 1393/01/28

Summary

According to the large number of third molar surgery and high incidence and prevalence of complications after this surgery and that there are many studies that confirmed the positive effects of an oily calcium hydroxide suspension on periodontal healing after surgical and non surgical treatments we decided to evaluation the effect of an oily calcium hydroxide suspension (osteora) on pain and complications after surgical removal of impacted third molar. Materials and Methods: This study will be conducted with double blinded sequential matched randomized clinical trial design on patient who will come to Surgical Department of Tehran Azad university of Medical Sciences and two private offices. All patients whom underwent this surgery will between 17-40 years old that have the indication for extracting wisdom tooth surgery; have bilateral third molar (in maxilla or mandible) and these teeth have the same criteria as in four point trauma rating scale and Pederson. Patients consciously agreed to this study and promising incorporation. Effect of OSTEORA will be evaluated on pain, healing, hemorrhage, dry socket and infection in different times. If this material have positive impact on pain, complications and healing after third molar surgery, could be alternative for various other drugs which have side effects.

Registrant information

Name

Saifollah Hemmat

Name of organization / entity

Bandarabbas University of Medical Sciences, Dental Faculty

Country

Iran (Islamic Republic of)

Phone

+98 76 1335 0573

Email address

hemmat.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

research center of azad dental university of tehran

Expected recruitment start date

2013-10-06, 1392/07/14

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of an oily calcium hydroxide suspension on pain and complications after surgical removal of impacted third molar

Public title

effect of an oily calcium hydroxide suspensin on complications after third molar surgery

Purpose

Prevention

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040717166N1**

Registration date: **2014-04-17, 1393/01/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

All patients whom underwent this surgery were between 17-40 years old that had the indication for exacting wisdom tooth surgery; had bilateral teeth (maxilla or mandible) and these teeth had the same criteria as in four point trauma rating scale and Pederson. Patients consciously agreed to cooperate with this study and promising incorporation. patients will be excluded if: having acute or chronic pericoronitis; using drugs except the drugs which were considered in the study; their disinclination for evaluation; not filling out or handing the forms; having systemic problems; pregnancy; considered drug prohibition for the patient; having allergic history to the considered drug; having painful conditions in the mouth like having teeth with root canal therapy indication; having any algogenic condition in the body; having nervous system diseases; having a need for prophylaxis; patients using steroids, antidepressant, antibiotics, analgesics; having complications during surgery; inferior alveolar canal exposure; applying more traumatic pressure in one side; having the condition that four bony walls were not available for putting the material; condition were having same numbers of sutures were not possible; disability in suturing the flap completely.

Age

From **17 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

islamic azad university of medical sciences, dentistry faculty

Street address

no.4 , 10th neyestan, pasdaran street

City

tehran

Postal code

19486

Approval date

2011-12-11, 1390/09/20

Ethics committee reference number

13011

Health conditions studied**1****Description of health condition studied**

impacted third molar

ICD-10 code

k01.1

ICD-10 code description

Embedded and impacted teeth

Primary outcomes**1****Description**

pain

Timepoint

immediate,1,6,12,24,32,48,72 hours after surgery

Method of measurement

The amount of pain depending on VAS of pain

2**Description**

healing

Timepoint

immadiate,3 and 7 days after surgery

Method of measurement

with healing scale

3**Description**

dry socket

Timepoint

3-4 days after surgery

Method of measurement

inspection of signs and symptoms

4**Description**

infection

Timepoint

3-7 days after surgery

Method of measurement

inspection of signs and symptoms

5**Description**

bleeding

Timepoint

immediate,8-24 hours , 24-72 hours after surgery

Method of measurement

inspection of signs and symptoms

Secondary outcomes

empty

Intervention groups**1****Description**

intervention: after surgical removal of tooth ,the socket was chosen randomized and it was filled with OCHS (OSTEORA® 0.5 ml) until it got overfilled

Category

Prevention

2**Description**

control:after surgical removal of impacted third molar On the other side we just pretended to put it in the socket (control group) and the patient was convinced that we had put the material on the both sides

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

tehran azad university of medical sciences, dental faculty

Full name of responsible person

dr. saifollah hemmat

Street address

no.4 , 10th neyestan, pasdaran street

City

tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Reserch Center of Tehran azad university of medical sciences

Full name of responsible person

Naser Valayei

Street address

No.4 , 10th Neyestan, Pasdaran street

City

Tehran

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

Yes

Title of funding source

Reserch Center of Tehran azad 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**

tehran azad university of medical sciences, dental faculty

Full name of responsible person

dr. saifollah hemmat

Position

oral and maxillofacial surgen

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

no. 4 , 10th neyestan, pasdaran street

City

tehran

Postal code

19486

Phone

+98 21 2256 4570

Fax

+98 21 2256 4573

Email

info@dfau.com

Web page address

www.dentaliau.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

tehran azad university of medical sciences , dental faculty

Full name of responsible person

dr. saifollah hemmat

Position

oral and maxillofaial surgen

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

no.4, 10th neyestan, pasdaran street

City

tehran

Postal code

19486

Phone

+98 21 2256 4570

Fax

+98 21 2256 4573

Email

info@dfau.com

Web page address

www.dentaliau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

tehran azad university f medical sciences, dental
faculty

Full name of responsible person

dr. saifollah hemmat

Position

oral and maxillofacial surgeon

Other areas of specialty/work

Street address

no.4, 10th neyestan, pasdaran street

City

tehran

Postal code

19486

Phone

+98 21 2256 4570

Fax

+98 21 2256 4573

Email

info@dfau.com

Web page address

www.dentaliau.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