

# 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

##### 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.

#### 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**

2014-04-17, 1393/01/28

##### Registrant information

###### Name

Saifollah Hemmat

###### Name of organization / entity

Bandarabbas University of Medical Sciences, Dental Faculty

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### 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

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**

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www.dentaliau.ac.ir

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

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**Full name of responsible person**

dr. saifollah hemmat

**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

tehran azad university f medical sciences, dental  
faculty

**Full name of responsible person**

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**Position**

oral and maxillofacial surgeon

**Other areas of specialty/work**

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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*