

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Direct Pulp Capping with Propolis and Calcium Hydroxide versus Mineral Trioxide Aggregate on Formation of Dentin Bridge in patients who are candidate for extraction of the third molar: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of direct pulp capping with propolis, calcium hydroxide and mineral trioxide aggregate on formation of dentin bridge. **Design:** a double blinded randomized clinical trial. **Setting and conduct:** All eligible patients who are candidate for extraction of the third molar and will refer to the maxillofacial surgery ward of School of Dentistry of Hamadan during the study period will be enrolled. **Inclusion criteria:** (a) candidate for extraction of the third molar; (b) age of 20 to 30 years. **Exclusion criteria:** (a) presence of and dental caries in the third molar; (b) history of trauma to the third molar; (c) presence of lesion in periapical or periodontal area. **Intervention:** Direct pulp capping of the third molar with propolis at 3 to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually. **Control:** (a) Direct pulp capping of the third molar with calcium hydroxide at 3 to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually; (b) Direct pulp capping of the third molar with mineral trioxide aggregate at 3 to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually. **Primary outcome:** Formation of dentin bridge through assessing the third molar histologically 45 days after intervention. **Secondary outcome:** (a) presence of inflammation through assessing the third molar pulp histologically 45 days after intervention; (b) quality of the dentin bridge through assessing the third molar histologically 45 days after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403049014N30**

Registration date: **2014-03-11, 1392/12/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2014-04-09, 1393/01/20

Expected recruitment end date

2014-04-30, 1393/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Direct Pulp Capping with Propolis and Calcium Hydroxide versus Mineral Trioxide Aggregate on Formation of Dentin Bridge in patients who are candidate for extraction of the third molar: a double blinded randomized clinical trial

Public title

Effect of Direct Pulp Capping with Propolis and Calcium Hydroxide versus Mineral Trioxide Aggregate on Formation of Dentin Bridge in patients who are candidate for extraction of the third molar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) candidate for extraction of the third molar; (b) age of 20 to 30 years. Exclusion criteria: (a) presence of and dental caries in the third molar; (b) history of trauma to the third molar; (c) presence of lesion in periapical or periodontal area.

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control group systematically one at a time. Blinding: The three drugs will be prescribed during pulp capping thus the patients will not aware of the intervention. In addition, the pathologist, who will assess the formation of the dentin bridge, will not aware of the intervention. Therefore, the trial will be run double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-03-02, 1392/12/11

Ethics committee reference number

D/P/16/35/9/4196

Health conditions studied

1

Description of health condition studied

Formation of dentin bridge

ICD-10 code

K04.3

ICD-10 code description

Abnormal hard tissue formation in pulp

Primary outcomes

1

Description

Formation of dentin bridge

Timepoint

45 days after intervention

Method of measurement

through assessing the third molar histologically

Secondary outcomes

1

Description

presence of inflammation

Timepoint

45 days after intervention

Method of measurement

through assessing the third molar pulp histologically

2

Description

quality of the dentin bridge

Timepoint

45 days after intervention

Method of measurement

through assessing the third molar histologically

Intervention groups

1

Description

Direct pulp capping of the third molar with propolis at 3

to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually

Category

Treatment - Drugs

2

Description

Direct pulp capping of the third molar with calcium hydroxide at 3 to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually

Category

Treatment - Other

3

Description

Direct pulp capping of the third molar with mineral trioxide aggregate at 3 to 3.5 mm in depth, 4 to 4.5 mm width mesiodistally, and 3 to 3.5 mm width buccolingually

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr Golsa Salehi Mehr

Street address

School of Dentistry, Shahid Fahmideh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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

School of Dentistry

Full name of responsible person

Dr Golsa Salehi Mehr

Position

Resident of Endodontic

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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shahriari1390@yahoo.com

Web page address

Person responsible for updating data

Contact

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