

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Histological Evaluation of Pulp Tissue Following Direct Pulp Capping with Propolis and Dycal

Protocol summary

Summary

The aim of present study sought to histologically assess and compare pulp tissue following pulp capping with propolis and Dycal A cavity was prepared in the center of the occlusal surface of 10 human third molars that no traumatic, carious, periapical or periodontal lesions existed using a cylindrical bur. The pulp was exposed with a round bur. Samples were randomly divided into two groups. The first group underwent direct pulp capping with propolis and the second group with Dycal. Autopolymerizing glass ionomer was then applied to seal the area. The teeth were extracted after 45 days and histologically evaluated. presence of inflammation, its severity, formation of dentinal bridge and its quality and quantity and presence of odontoblast-like cells were assessed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031712832N1**

Registration date: **2013-06-09, 1392/03/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-09, 1392/03/19

Registrant information

Name

Zohreh Ahangari

Name of organization / entity

Dental school shahid Beheshti Medical university of
Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2013-05-01, 1392/02/11

Expected recruitment end date

2013-11-01, 1392/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histological Evaluation of Pulp Tissue Following Direct
Pulp Capping with Propolis and Dycal

Public title

Propolis effect on dental pulp

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Vital third molars Exclusion criteria:
Previous trauma; carious lesion; periapical lesions;
periodontal lesions

Age

From **20 years** old to **28 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research of Dental School of Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blvd, Evin

City

Tehran

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

-

Health conditions studied

1

Description of health condition studied

Dental carries and Pulp involvment

ICD-10 code

K02.8

ICD-10 code description

K02.8 Other dental caries

2

Description of health condition studied

Dental carries and Pulp involvment

ICD-10 code

K04.3

ICD-10 code description

Abnormal hard tissue formation in pulp

Primary outcomes

1

Description

Direct pulp cap

Timepoint

45

Method of measurement

Histologic Evaluation

Secondary outcomes

1

Description

Severity of inflammation

Timepoint

After 45 days

Method of measurement

Histologic Evaluation

2

Description

Quality of newly formed dentin, Quantity of the newly formed dentin,

Timepoint

After 45 days

Method of measurement

Histologic Evaluation

3

Description

Presence of odontoblast-like cells

Timepoint

After 45 days

Method of measurement

Histologic Evaluation

Intervention groups

1

Description

The teeth were disinfected Local anesthesia was induced, rubber dam was placed and an occlusal cavity was prepared using a sterile cylindrical diamond bur and high speed hand piece with air-water spray as the coolant. The prepared cavity measured 3-3.5 mm in depth, 4-4.5 mm in mesiodistal width and 3-3.5 mm in buccolingual width. The mentioned measurements were done using a periodontal probe. Pulp chamber was exposed at the center of the pulp chamber roof using a round diamond bur with air-water spray. Hemostasis was achieved by mild pressure of a moist cotton ball at the exposure site. The exposure site was then completely dried with a dry cotton ball. This procedure was repeated until achieving complete hemostasis. If hemostasis was not achieved after 5 minutes of using a cotton ball, the sample was excluded from the study. The teeth were divided into two groups of 5 samples each. The exposure site in group one was covered with Dycal (control groups)

Category

Treatment - Drugs

2

Description

The teeth were disinfected . Local anesthesia was induced, rubber dam was placed and an occlusal cavity was prepared using a sterile cylindrical diamond bur and high speed hand piece with air-water spray as the coolant. The prepared cavity measured 3-3.5 mm in depth, 4-4.5 mm in mesiodistal width and 3-3.5 mm in buccolingual width. The mentioned measurements were done using a periodontal probe. Pulp chamber was exposed at the center of the pulp chamber roof using a round diamond bur with air-water spray. Hemostasis was achieved by mild pressure of a moist cotton ball at the exposure site. The exposure site was then completely dried with a dry cotton ball. This procedure was repeated until achieving complete hemostasis. If hemostasis was not achieved after 5 minutes of using a cotton ball, the sample was excluded from the study. The teeth were divided into two groups of 5 samples each in group two with propolis(experimental groups).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic Dept. of Dental school of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr zohreh ahangari

Street address

Daneshjoo Blvd, Evin

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental school of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr maryam moezizadeh

Street address

Daneshjoo Blvd, Evin

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dental school of Shahid Beheshti 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

Dental school of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Zohreh Ahangari

Position

Associate Professor, Endodontist

Other areas of specialty/work

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Full name of responsible person

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Associate Professor, Endodontist

Other areas of specialty/work

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Fax

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