Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the histopathology of primary teeth pulp after direct pulp capping by Nano-emulsion containing Propolis and Nigella-sativa: Randomized Clinical Trial

Protocol summary

Study aim

Evaluating the histopathology of primary teeth pulp after direct pulp capping by Nano-emulsion containing Propolis and Nigella-sativa: Randomized Clinical Trial

Design

This clinical trial would be run while it includes control group, consisting parallel groups, without blinding, with randomization (block randomization), in order to investigate the efficacy of a herbal extract on 10 patient.

Settings and conduct

This study will be accomplished in the pediatric department of Shahed dental school on children who needs to extract their mandibular canine due to orthodontic reasons (considering the exclusion and inclusion criteria). After cavity preparation and exposing the pulp, the agents (propolis- nigella sativa in intervention or the MTA in control group) would be applied on pulp cells and the teeth will be restored. Subsequently, teeth will be extracted (due to orthodontic treatment plan not due to our study) and their histopathology will be studied.

Participants/Inclusion and exclusion criteria

6 to 9 years old children whose both mandibular canines has to be extracted in future two months due to orthodontic reason (serial extraction); these teeth should not have sever root resorption or caries induced pulpitis

Intervention groups

intervention group: after exposing the tooth pulp, the propolis-nigella sativa extract would be applied on the pul cells. Control group: after exposing the tooth pulp, the MTA agent would be applied on the pul cells.

Main outcome variables

The inflammatory status of pulp; the amount of cell differentiation in pulp; the amount of dentine bridge formation in pulp.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230312057689N1**
Registration date: **2023-04-02, 1402/01/13**
Registration timing: **prospective**

Last update: **2023-04-02, 1402/01/13**
Update count: **0**

Registration date

2023-04-02, 1402/01/13

Registrant information

Name

Faeze Hamze

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 9210

Email address

f.hamzeh@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the histopathology of primary teeth pulp after direct pulp capping by Nano-emulsion containing Propolis and Nigella-sativa: Randomized Clinical Trial

Public title
Effect of Propolis-Nigella sativa extract on primary tooth pulp

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
6-9 years old without any systemic disorder no allergy to dental anesthesia two existing mandibular canine required to be extracted due to orthodontic reason the patient and his/her parents are eager to participate in the study

Exclusion criteria:
the mentioned canine teeth have root resorption more than apical third the mentioned canine have irreversible pulpitis

Age
From **6 years** old to **9 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the Random allocation rule will be used. According to two main treatment agents including the propolis- nigella sativa or MTA agents, 20 cards will be prepared. On half of the cards (n=10) the A code (regarding the propolis-nigella sativa), and on other half, the B code (regarding the MTA agent) will be written. Afterwards, the cards will be kept in opaque pockets and stored in lottery container. At the beginning of the procedure, the dentist will chose one pocket and according to the code, the MTA or the propolis-nigella sativa will be used for treatment of the first tooth. Selection of the pockets will not have any replacement and the selected pocket will be discarded after recording of the agent.

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
Ethics committee of Shahed University

Street address
Ethics committee, Shahed University, Opposite to Imam Khomeini Holy Shrine, Persian Gulf Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2023-02-27, 1401/12/08

Ethics committee reference number
IR.SHAHED.REC.1401.167

Health conditions studied

1

Description of health condition studied
pulpitis (pulp capping)

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
percentage of dentine bridge formation

Timepoint
two months after intervention

Method of measurement
optical microscope

Secondary outcomes

1

Description
The intensity of the presence of inflammatory cells

Timepoint
two months after intervention

Method of measurement
optical microscope

Intervention groups

1

Description
Intervention group: According to the randomization code,

cavity preparation will be accomplished on one of the mandibular canine (left or right) until pulp exposure would occur. Thereafter, the propolis-nigella sativa extract (which will be produce by the present researchers) will be applied on dental pulp cells and the tooth will be restored. Two months later, based on orthodontic reason (serial extraction), the mentioned tooth will be extracted (extracting of the tooth is not related to the study process at all).

Category

Treatment - Drugs

2

Description

Control group: According to the randomization code, cavity preparation will be accomplished on one of the mandibular canine (left or right) until pulp exposure would occur. Thereafter, the MTA agent (Dentsply comany, USA) will be applied on dental pulp cells and the tooth will be restored. Two months later, based on orthodontic reason (serial extraction), the mentioned tooth will be extracted (extracting of the tooth is not related to the study process at all).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Department, Shehed Dental School

Full name of responsible person

Faeze Hamze

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Shahed Dental School, Italia St., Vesal Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

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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

Shahed University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Faeze Hamze

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Contact

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Pat of the data will accessible including the results regarding the histopathology evaluation would be published
When the data will become available and for how long
The access will be available from the Autumn of 2023
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
If the researchers need our available data to conduct similar research.
From where data/document is obtainable
Faeze Hamze, 00983432476498, Faeze.hamze@gmail.com
What processes are involved for a request to access data/document
After completing the data collection, by sending an email to the provided email and explaining the reason for the need to access the data.
Comments