

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Clinical and radiographical evaluation of Allium Sativum oil compared with MTA in primary molar pulpotomy in children

Protocol summary

Study aim

To compare the clinical and radiographic differences of MTA and Garlic oil in pulpotomy of the first and second primary molars of children.

Design

All selected teeth were randomly divided into two groups each containing 45 samples, depending on the type of medicament used. Randomization was done by coin.

Settings and conduct

Shahed Dental School, Pediatric department

Participants/Inclusion and exclusion criteria

Inclusion criteria : These children were systemically healthy and had not used antibiotic in the last 14 days and had sufficient cooperation (Frankel 3 and 4), and on the strength of a complete history and clinical and radiographic examination, at least had two decayed asymptomatic primary molars, with the possibility of pulp exposure during cavity preparation.

Intervention groups

After topical gel, anesthesia was induced. All caries were removed. After rinsing with saline one or more sterile cotton pellets moistened with distilled water were placed over the pulp stumps, and gentle pressure was applied for 5 minutes for obtaining hemostasis. Randomly pulp stumps of molars in one side were dressed with a cotton pellet damped with Allium sativum oil (Noshad company registration number 1228208638 IRC) for 1 minute. And on the other side MTA was used for 1 min. The access cavity was sealed with a thick mix of ZOE cement (Kemdent) followed with SSC(3M) in proper size. Cementation was done with Glass ionomer (GC1 Japan LUTING CEMENT)

Main outcome variables

The clinical success rate after 3 and 6 months was 100% in both groups. The radiographic success rates after 3 months and 6 months in the ALL group were 91.1% and 75.6, respectively, and in the MTA group were 95.6% and 91.1%, respectively. The difference between the two groups was not statistically significant.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190313043046N1**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **retrospective**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

Registration date

2019-04-29, 1398/02/09

Registrant information

Name

Taraneh Faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 7571

Email address

trnfaghihi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-29, 1396/07/07

Expected recruitment end date

2018-09-29, 1397/07/07

Actual recruitment start date

2017-09-29, 1396/07/07

Actual recruitment end date

2018-09-29, 1397/07/07

Trial completion date

2018-09-29, 1397/07/07

Scientific title

Clinical and radiographical evaluation of Allium Sativum oil compared with MTA in primary molar pulpotomy in children		Postal code 1417755351
Public title Clinical and radiographical evaluation of Allium Sativum oil compared with MTA in primary molar pulpotomy in children		Approval date 2017-08-28, 1396/06/06
Purpose Education/Guidance		Ethics committee reference number IR.Shahed.REC.1396.87
Inclusion/Exclusion criteria Inclusion criteria: These children were systemically healthy at least Not used antibiotic in the last 14 days Had two decayed asymptomatic primary molars, with the possibility of pulp exposure during cavity preparation. Exclusion criteria:		Health conditions studied
Age No age limit		<u>1</u>
Gender Both		Description of health condition studied Clinical and radiographical evaluation of Allium Sativum oil in comparison with MTA in primary molar pulpotomy
Phase N/A		ICD-10 code ICD-10 code description
Groups that have been masked <i>No information</i>		Primary outcomes
Sample size Target sample size: 90 Actual sample size reached: 45		<u>1</u>
Randomization (investigator's opinion) Randomized		Description Clinical effect of Allium Sativum oil
Randomization description simple randomization with table of random numbers unit of randomization individual		Timepoint Clinical and radiographical evaluation of Allium Sativum oil in comparison with MTA in primary molar pulpotomy in 3 and 6 months follow-up
Blinding (investigator's opinion) Double blinded		Method of measurement According to zurne and seale criteria
Blinding description patient and analyzer are blind		Secondary outcomes empty
Placebo Not used		Intervention groups
Assignment Parallel		<u>1</u>
Other design features		Description Intervention group: Randomly pulp stumps of molars in one side were dressed with a cotton pellet damped with allium sativum oil (Noshad company registration number 1228208638 IRC) for 1 minute.
Secondary Ids empty		Category Other
Ethics committees		<u>2</u>
<u>1</u>		Description Intervention group: After pulpotomy on the other side MTA was prepared according to manufacturer`s instructions and condensed lightly with a moistened sterile cotton pellet to ensure a thickness of 2 to 3 mm
Ethics committee Name of ethics committee The Ethical Committee of Shahed University. (IR.Shahed.REC.1396.88)		Category Other
Street address Dental School, Shahed University, Italy St, Vesal Ave, Keshavarz Blv, Tehran, IR Iran		Recruitment centers
City Tehran		<u>1</u>
Province Tehran		Recruitment center Name of recruitment center

Shahed dental school

Full name of responsible person

Taraneh Faghihi

Street address

Dental School, Shahed University, Italy St, Vesal Ave,
Keshavarz Blv, Tehran, IR Iran

City

Tehran

Province

Tehran

Postal code

1417755351

Phone

+98 21 8895 9210

Email

trnfaghihi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr Roza Haghgoo

Street address

Dental School, Shahed University, Italy St, Vesal Ave,
Keshavarz Blv, Tehran, IR Iran

City

Tehran

Province

Tehran

Postal code

1417755351

Phone

+98 21 8895 9210

Email

haghgoodent@yahoo.com

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

1

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Taraneh faghihi

Position

Resident of Pediatric Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

only results of the study would be identified

When the data will become available and for how long

from summer 2019 they would be accessible

To whom data/document is available

for everyone

Under which criteria data/document could be used

no specific limitations

From where data/document is obtainable

trnfaghihi@gmail.com

What processes are involved for a request to access data/document

maximum 2 weeks after sending request to the email

Comments