

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of clinical and radiographic success rate and pain after pulpotomy in primary molars using standardized extract of myrtle (*Myrtus communis* L.) leaves and formocresol: a double blind randomized clinical trial

Protocol summary

Study aim

Comparison of clinical and radiographic success rate and pain after pulpotomy in primary molars using standardized extract of myrtle (*Myrtus communis* L.) leaves and formocresol: a double blind randomized clinical trial

Design

Clinical trials with control, interventional, blind, and randomized control groups

Settings and conduct

This project will be carried out in the Department of Pediatrics of the Kerman School of Dentistry. Before treatment, adequate explanations will be given on the clinical approach and treatment logic as well as possible risks to the parents. Pulpotomy treatment of all teeth will be done by a specialized dentistry assistant and supervised by the relevant teacher. Follow up evaluations are carried out by two researchers who are not familiar with the type of treatment and will comment on radiographic criteria.

Participants/Inclusion and exclusion criteria

pulp exposure due to caries, no pathologic mobility, No history of spontaneous pain , no sinus tracts , abscess or swelling, Restorable teeth with ssc , hemostasis could be easily achievable, No internal or pathologic external root resorption, No interradicular or periapical radiolucency

Intervention groups

Group 1: Formocresol Group 2: Myrtus Extract

Main outcome variables

Mutation and cytogenic effect of formocresol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039725N1**

Registration date: **2018-12-06, 1397/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-06, 1397/09/15**

Update count: **0**

Registration date

2018-12-06, 1397/09/15

Registrant information

Name

fatemeh mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3638 3952

Email address

fa.mohamadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical and radiographic success rate and pain after pulpotomy in primary molars using

standardized extract of myrtle (Myrtus communis L.)
leaves and formocresol: a double blind randomized
clinical trial

Public title

Comparison of clinical and radiographic success rate and
pain after pulpotomy using standardized extract of
myrtle (Myrtus communis L.) leaves and formocresol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

pulp exposure due to caries, no pathologic mobility, No
history of spontaneous pain , no sinus tracts , abscess or
swelling, Restorable teeth with ssc , hemostasis could be
easily achievable, No internal or pathologic external root
resorption, No intraradicular or periapical radiolucency

Exclusion criteria:

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Through the random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Follow up evaluations are carried out by two researchers
who are not aware of the type of treatment and will
comment on radiographic criteria. The statistician is not
aware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical
Sciences

Street address

Shafa Ave

City

Kerman

Province

Kerman

Postal code

7618759689

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.KMU.REC.1397.322

Health conditions studied

1

Description of health condition studied

pulp disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mutation and cytogenic effect of formocresol

Timepoint

0,6,12 month

Method of measurement

radiographic and clinical finding , and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group 1: Cotton impregnated with
Formocresol (Sultan, USA) for 5 minutes Group 2: Cotton
impregnated with Myrtus extract for 30 Min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry

Full name of responsible person

fatemeh mohammadi

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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
Kerman University of Medical Sciences
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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
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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

2

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
abbas pardakhti
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Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
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Position
resident
Latest degree
Specialist
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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

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 part of the information, such as the original outcome information, is shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

-

From where data/document is obtainable

f.mohammadi4045@gmail.com

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

1 month

Comments