

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Citrullus colocynthis (L.) Schrad oil and Dentol drop on tooth pain reduction: Double blind randomized clinical trial

Protocol summary

Study aim

Comparison study of Citrullus Colocynthis (L.) schrad oil and Dentol drop on tooth pain reduction

Design

Clinical trial with control group, with parallel groups, blind, randomized With a sample size of 60 people

Settings and conduct

The study will be carried out at the Dental Clinic of Khorram-Abad Dental College, Lorestan University of Medical Sciences. Persons entering the study will receive written consent consciously and the questionnaire will be completed through the interview. Through the Visual Analogue Scale, The patient's pain number is recorded. Then the drug is placed on the pain location and after 10 minutes the drug is removed from the patient's mouth and the patient's pain number is re-recorded. The data is compared and the final report is prepared. For blinding, drugs are encoded in the same packages by the original investigator and delivered to responsible for collecting data who is unaware of the contents of the packages and is selected by sortition a package for each patient. The patient will also be unaware of the drug given to him.

Participants/Inclusion and exclusion criteria

Entry conditions: Age of 40-18 years, Tooth pain Exit Conditions: Pregnancy, Hypertension, Diabetes, Heart disease, Immune system disorders, Unwillingness to cooperate

Intervention groups

Group 1: Cotton bullet impregnated with 0.2 ml of Citrullus Colocynthis (L.) schrad oil is applied locally to the tooth that is in pain for 10 minutes. Group 2: Cotton bullet impregnated with 0.2 ml of Dentol drop is applied locally to the tooth that is in pain for 10 minutes. Group 3: Cotton bullet impregnated with 0.2 ml of sesame oil (placebo) is applied locally to the tooth that is in pain for 10 minutes.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181230042172N1**

Registration date: **2019-01-20, 1397/10/30**

Registration timing: **prospective**

Last update: **2019-01-20, 1397/10/30**

Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Ehsan Hamzelouei Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3320 7826

Email address

hamzelouei.e@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-24, 1397/11/04

Expected recruitment end date

2019-02-23, 1397/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Citrullus colocynthis (L.) Schrad oil and Dentol drop on tooth pain reduction: Double blind randomized clinical trial

Public title

Comparison of Citrullus colocynthis (L.) Schrad oil and Dentol drop on tooth pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy clients suffering from tooth pain referring to the dental clinic of Khorramabad dental college, Lorestan University of Medical Sciences in 2019 Those aged 18 to 40 years old

Exclusion criteria:

Pregnants Patients in ASA II or more health status Patients have taken analgesics and antibiotics in 12 hours before the test Fail in cooperation Those who have a history of allergy to Citrullus colocynthis (L.) Schrad Those who use drug and alcohol Those who have a disorder of the immune system

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done based on Sortition

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome evaluator and patients are kept blind. Test samples are coded in similar size and packages by investigator and it is given to the outcome evaluator, who is unaware of the contents of each package. After obtainig informed consent from the patient and the necessary explanations about the study and their safety and completing the questionnaire. Then clinician will take one of the packages and write the code in questionnaire before starting the test.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Deputy of research and technology, Lorestan University of Medical Sciences, Academic Complex Kamalvand

City

Khorramabad

Province

Lorestan

Postal code

6814989468

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.LUMS.REC.1397.141

Health conditions studied

1

Description of health condition studied

Tooth pain

ICD-10 code

K04.0

ICD-10 code description

Diseases of pulp and periapical tissues-Pulpitis-irreversible

Primary outcomes

1

Description

Score pain severity on the Visual Analogue Scale

Timepoint

Before the intervention and 10 minutes after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cotton bullet impregnated with 0.2 ml of Citrullus colocynthis (L.) Schrad TOUBA company topically for 10 minutes on a tooth that is painful

Category

Treatment - Drugs

2

Description

Intervention group: Cotton bullet impregnated with 0.2 ml of Dentol drop Khorraman company topically for 10 minutes on a tooth that is painful.

Category

Treatment - Drugs

3

Description

Control group: Cotton bullet impregnated with 0.2 ml of sesame oil topically for 10 minutes on a tooth that is painful.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dental College, Khorramabad University of Medical Sciences

Full name of responsible person

Ehsan Hamzelouei Moghadam

Street address

Razi St., Khorramabad Dental College

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6813833946

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Sara Mohammadi Sepahvand

Street address

Razi St., Khorram-Abad College of Dentistry

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smohammadis@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ehsan Hamzelouei Moghadam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mina Asadzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is accessible after being unrecognizable

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All researchers have access to data

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Dental College, Lorestan University of Medical Sciences

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

There is no particular process

Comments