

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparative evaluation of the effect of ibuprofen lysine & gelofen - acetaminophen on postoperative endodontic dental pain with irreversible pulpitis

Protocol summary

Study aim

to determine the effect of ibuprofen lysine with acetaminophen & gelofen after root canal therapy in teeth with irreversible pulpitis

Design

Clinical trial has a control group with parallel intervention, single blinded and randomise

Settings and conduct

The subjects were 60 people who were selected from individuals referring to the department of Endodontics of Kermanshah Dentistry School. Individuals are randomly divided into two groups of intervention and control. The type of intervention in the envelopes with A, B name Have been placed and the person giving the envelopes to patients is blinded to the type of intervention in each envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for Root therapy Age over 12 years Ability to read and understand the visual analog scale Exclusion criteria: Use of other anti pain drug before treatment; Cystic teeth; Hopless teeth; sensitivity to the drugs present in the study; Age under 12 years ;liver problems; history of chemotherapy; Inability to read and understand the visual analog scale; Heart problems; Kidney disease; Stomach problem

Intervention groups

The intervention group 1 includes those who receive ibuprofen lysine 400 mg. The intervention group 2 contains people who receive gelofen 400 mg and acetaminophen 500 mg.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140527017880N8**

Registration date: **2019-07-29, 1398/05/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-29, 1398/05/07**

Update count: **0**

Registration date

2019-07-29, 1398/05/07

Registrant information

Name

Roohollah Sharifi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1722 2400

Email address

r.sharifi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effect of ibuprofen lysine

& gelofen - acetaminophen on postoperative endodontic dental pain with irreversible pulpitis

Public title

Comparative evaluation of the effect of ibuprofen lysine & gelofen - acetaminophen on pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for Root thtapy Age over 12 years Ability to read and understand the visual analog scale

Exclusion criteria:

Useof other anti pain drug befor treatment Cystic teeth Hopless teeth sensitivity to the drugs present in the study Age under 12 years liver problems history of chemotherapy Heart problems Kidney disease Stomach problem

Age

From **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

.We prepare 2 group packes first A and second B We put in A packets ibubrofenlysin and in packets B gelofen with asetaminophen acourding to randomization number table . packets A goes to pair number and packets B goes to unique number patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and who share the packets are unaware of packets contain

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Shahid beheshti Blvd.Building number 2

City

Kermanshah

Province

Kermanshah

Postal code

67146673159

Approval date

2019-03-21, 1398/01/01

Ethics committee reference number

IR.KUMS.REC.1398.134

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain

Timepoint

8,16,24 and 48 hour after treatment

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

30 patients received ibuprofen-lysine coated tablets at a dose of 400 mg after treatment.

Category

Treatment - Drugs

2

Description

Control group: 30 patients received gelofen 400 mg with acetaminophen 500 mg after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Root Therapy, School of Dentistry,

Kermanshah University of Medical Sciences
Full name of responsible person
roholah sharifi
Street address
Shariati Street, above Shura Street
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roholahsharifi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid najafi
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6715847141
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Fax
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farid_n32@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

56

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

Kermanshah University of Medical Sciences
Full name of responsible person
Rohola Sharifi
Position
Associate professor
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

all data after Unidentifiable can be potentially publish

When the data will become available and for how long

Start the access period 3 months after printing results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

.

From where data/document is obtainable

dr roholla sharifi tel:09122177490

imail:r.sharifi@kums.ac.ir

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

The responsible person is transferred

Comments