Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim
to determine the effect of ibubrofenlysine with asetaminophen&gelofen after root canal therapy in teeth with ireversibie 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

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Roohollah Sharifi

Name of organization / entity
Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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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 pulpaitis

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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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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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
Roholla Sharifi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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
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What processes are involved for a request to access data/document
The responsible person is transferred
Comments