Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between different ibuprophen formulations with two prescription methods on postoperative pain after root canal treatment of teeth with symptomatic irreversible pulpitis; a double blind randomized clinical trial

Protocol summary

Summary

1-objectives:Comparison between different ibuprophen formulations with two prescription methods on postoperative pain after root canal treatment of teeth with symptomatic irreversible pulpitis 2.design:4groups of 30 people are selected double blined and randomise. 3.setting and conduct:using the random number table,patients will be selected and given medication. 4.participants including major eligibility criteria:age,type of pulpitis,systemic diseases. 5.intervention:patients use ibuprofen or ibuprofen lysine regulary or as needed. 6.main outcome measures:pain level every 6 hours to 72 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051934030N1**
Registration date: **2017-07-24, 1396/05/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

Name
sanaz Beyraghdar kashkooli
Name of organization / entity
shahid beheshti dental school
Country
Iran (Islamic Republic of)
Phone
+98 71 3633 3120
Email address
s_beyraghdar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between different ibuprophen formulations with two prescription methods on postoperative pain after root canal treatment of teeth with symptomatic irreversible pulpitis; a double blind randomized clinical trial

Public title

Effect of ibuprofen and ibuprofen lysine on pain after root canal treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1.Healthy patient with a first or second mandibular or maxillary molar tooth with irreversible pulpitis and have moderate to sever pain to the cold pulp test at the time of treatment and do not have periapical radiolucency appearance without sensivity to percussion. 2.All the patient have no clinical swelling. 3.No patient

had a draining sinus tract. 4.A positive response to an electrical pulp teste in addition to a prolonge response with moderate to sever pain to a cold pulp test (endo-Ice) confirmed the clinical diagnosos of acute irreversible pulpitis for each tooth. exclusion criteria : 1.Patients under 18. 2.The presence of any systemic disorders sensivity that prevent the use of ibuprophen. 3.Patient are allergic to local anesthetetics or sulfites. 4.Having a tooth not suitable for restoration or having serious pweriodontal disease that render the tooth unsuitable for endodontic treatment. 5.Patients who have use any type of analgesic medication. 6.Patient are unable to give informed consent. 7.Pregnant patient or breast fiding during study. 8.Failure to provide pain relief. 9.History of peptic ulcer or GI bleeding.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid beheshti universsty of medical sciences, dental school

Street address
Tehran-velenjak-daneshjoo boulevard

City
Tehran

Postal code

Approval date
2017-02-18, 1395/11/30

Ethics committee reference number
IR.SBMU.RIDS.REC.1395.398

Health conditions studied

1

Description of health condition studied
Pain after root canal treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The amount of pain after root canal treatment

Timepoint
every 6 hour to 72 hour after root canal treatment

Method of measurement
Visual analogue scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
intervention group1: will use Ibuprophen 400 mg or Ibuprophen lysine 400g regulary every 6 hours at least 24 hours. Patients should mark the severity of their pain in the VAS.

Category
Treatment - Drugs

2

Description
intervention group 2:will use Ibuprophen 400 mg or Ibuprophen lysine 400g , if necessary. In the patients description the maximum dose is prescribed. Patients should mark the severity of their pain in the VAS.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
shahid beheshti university of medical sciences-dental school-department of endodantics

Full name of responsible person
Dr ali haeri tabatabaei

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid beheshti dental school
Full name of responsible person
sanaz beyraghdar kashkooli
Street address
tehran-jamalzadeh south-shahid beheshti detal school internationl branch
City
tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahid beheshti dental school
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty