Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation and Comparison the effects of amitriptyline, ibuprofen and placebo in patients with irreversible pulpitis

Protocol summary

Study aim

compare the prophylactic effects of amitriptyline 25 mg, ibuprofen 400mg and placebo in patients with irreversible pulpitis to control pain and complete anesthetic effects.

Design

Double-blind randomized clinical trial with parallel groups design of 60 adult patients

Settings and conduct

This study was conducted in endodontic ward of Isfahan Dentistry college.Patients were randomly assigned to one of three study groups(similar Capsules were filled with one of medicines: Amitriptyline 25mg,ibuprofen 400 mg and placebo)patients,researcher and health care providers were not aware of type of drugs.Medications were administered as a single dose and at least 60-90 minutes before procedure..pain score were recorded on the Visual Analogue Scale,in different time :before, during and after procedure.

Participants/Inclusion and exclusion criteria

Entry requirements: Age>18 years old,Healthy candidates with no specific systemic diseases,Do not using any analgesic drugs within 4 hours before referral,Diagnosis of irreversible pulpitis based on pulp vitality tests;Non-entry conditions:Using analgesic drugs before refer,Medical allergy to NSAIDs and Amitriptyline,Teeth with a history of trauma and teeth that have recently been endodontically or orthodontically experienced in the last 6 months,Pregnancy and Lactation

Intervention groups

First group:Patients who received Amitriptyline 25mg capsule orally,second group:Patients who received Ibuprofen 400 mg capsule orally.Control group:Patients who received Placebo capsule that include Starch powder

Main outcome variables

Amitriptyline 25mg,ibuprofen 400mg and placebo had same effect on pain control during the endodontics procedure.The type of treated teeth had no effect on drug performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N2**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **retrospective**

Last update: **2020-07-04, 1399/04/14**
Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

behrooz heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8699

Email address

b.heydari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-11-22, 1397/09/01

Actual recruitment end date

2019-04-09, 1398/01/20

Trial completion date
2019-04-09, 1398/01/20

Scientific title
Evaluation and Comparison the effects of amitriptyline, ibuprofen and placebo in patients with irreversible pulpitis

Public title
Evaluation and Comparison the effects of amitriptyline, ibuprofen and placebo in patients with irreversible pulpitis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy candidates with no specific systemic diseases(specially heart,hepatic and renal diseases) Do not use any analgesic drugs within 4 hours before referral Diagnosis of irreversible pulpitis based on pulp vitality tests

Exclusion criteria:
Using analgesic drugs before refer Medical allergy to NSAIDs and Amitriptyline Teeth with a history of trauma and teeth that have recently been endodontically or orthodontically experienced in the last 6 months Pregnancy and Lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study participants, dentists, and researcher unaware of the assigned intervention. Patients in three groups received medications in the same package.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study participants, health care provider and researcher unaware of the assigned intervention. Patients in three groups received medications in the same package.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of yazd university of medical sciences

Street address
shahid sadoughi university of medical science,shohadaye Gomnam Blvd,Alem Sq

City
yazd

Province
Yazd

Postal code
8915173143

Approval date
2018-11-27, 1397/09/06

Ethics committee reference number
IR.SSU.MEDICINE.REC.1397.135

Health conditions studied

1

Description of health condition studied
irreversible pulpitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Reduction in patient pain score

Timepoint
Pain score on presentation,Pain score during injection,Pain score during procedure,Pain score at home(the first 6-8 hours)

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Amitriptyline 25mg, 1 or 2 hours before injecting the Anesthetic drug,patient receive one of the same capsules orally.manufactured by Daru Pakhsh

Category

Treatment - Drugs

2

Description
Intervention group: Ibuprofen 400 mg,1 or 2 hours before injecting the Anesthetic drug,patient receive one of the same capsules orally.manufactured by Raha Pharmaceutical Isfahan
Category
Treatment - Drugs

3

Description
Control group: Placebo,Starch powder,1 or 2 hours before injecting the Anesthetic drug,patient receive one of the same capsules orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University Of Medical Sciences,Dentistry college
Full name of responsible person
Jalil modaresi
Street address
Isfahan University of medical sciences,Hezar jarib Ave,Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Fax
+98 31 3668 2006
Email
education@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
مسعود میرزایی
Street address
shahid sadoughi university of medical sciences,shahidan Gomnam Blvd,Alem Sq
City
yazd
Province
Yazd
Postal code
8915173149
Email
b.heydari@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
behrooz heydari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Clinical Pharmacy
Street address
shahid sadoughi university of medical sciences,shohadaye Gomnam Blvd,Alem Sq
City
yazd
Province
Yazd
Postal code
8915173143
Phone
+98 35 3820 3410
Email
b.heydari@ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
behrooz heydari
Position
Assistant professor
Latest degree

Ph.D.

Other areas of specialty/work

Clinical pharmacy

Street address

shahid sadoughi university of medical sciences,shohadaye Gomnam Blvd,Alem Sq

City

yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behrooz heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

Shahid Sadoughi University of medical sciences,Shohadaye Gomnam Blvd,Alem Sq

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yazd

Province

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Postal code

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+98 35 3820 3410

Email

b.heydari@ssu.ac.ir

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

After nonrecognition, all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

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

Request your information by email. The data will be sent after a week.

Comments