

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of the analgesic effect of Anahil Plus and ibuprofen on pain after root canal treatment: a clinical trial study

Protocol summary

Study aim

Evaluation of analgesic effect of ibuprofen and Anahil Plus on postendodontic pain

Design

A clinical trial with parallel, single-blind, randomized, phase 2-3 groups on 78 patients. The process of randomization is done by Random allocation software.

Settings and conduct

the control group receives ibuprofen tablets and the intervention group receives Anahil Plus capsules. infra alveolar nerve block is done by injection of 1.8ml of lidocaine. After tooth isolation, tooth preparation will be done. Length determination is performed with the help of periapical radiography. Cleaning and shaping are done using the passive step-back technique. Saline and hypochlorite 2% are used as a cleanser. The canals are then dried with a paper cone and gutted laterally with gutta-percha and AH26 sealer. Patients are asked to record the pain score before drug use, 6, 12, and 24 hours after endo treatment. all steps are done in a private clinic.

Participants/Inclusion and exclusion criteria

inclusion criteria: Healthy patients aged 20 to 50 years with posterior teeth with irreversible pulpitis, radiographically normal teeth without any lesions
exclusion criteria: Patients using a drug that interferes with NSAIDs or lidocaine, systemic disease, pregnancy or lactation, allergy to Pineapple, celery, carrot, and fennel, aggressive periodontal disease, irreparable teeth

Intervention groups

control group includes 39 patients receiving ibuprofen 400mg tablets, saponin company, single-dose before endodontic treatment; intervention group includes 39 patients receiving Anahil Plus capsules containing 150 mg of bromelain and 300 mg of turmeric, Permon Amin Health Company, single-dose before endodontic treatment

Main outcome variables

Pain intensity after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048627N1**

Registration date: **2020-10-16, 1399/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-16, 1399/07/25**

Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

Fateme Keshvaridoost

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3340 5474

Email address

f.keshvaridoost@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-19, 1399/06/29

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effect of Anahil Plus and ibuprofen on pain after root canal treatment: a clinical trial study

Public title

effect of Anahil Plus and Ibuprofen on pain after root canal treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients aged 20 to 50 years
Posterior teeth with irreversible pulpitis
Spontaneous pain with at least 30mm on Visual Analogue Scale
Radiographically normal teeth, without any lesions, without sinus tract and without acute periapical abscess
Normal patients according to the Hospital Anxiety and Depression Scale
Prolonged tooth response to pulp electrical test and Endo-ice test
Fill in and sign the consent form

Exclusion criteria:

Taking medication that interferes with Non Steroid Anti Inflammatory Drugs or Lidocaine
Existence of systemic disease
Pregnancy or breastfeeding
allergy to pineapple, celery, carrot and fennel
Consumers of anticoagulants
Existence of aggressive periodontal disease
unable to restore the tooth pain in more than one tooth

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is 2-step. In the first step, using a simple random sampling method, samples with inclusion criteria will be selected. In the second stage, the blocked randomization method will be used for random allocation. Using blocked randomization, samples are assigned to two groups. The blocked randomization process is done with random allocation software. The samples will be placed in thirteen hexagonal blocks as mentioned.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the type of medication, there is no possibility of double-blinding, so the person who records the pain score is blinded without knowing the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vali-asr Highway, Imam Square, Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.MAZUMS.REC.1399.601

Health conditions studied

1

Description of health condition studied

Post endodontic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain after endodontic treatment

Timepoint

6, 12 and 24 hours after endodontic treatment

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anahil Plus capsules containing 150 mg of bromelain and 300 mg of turmeric, Permon Amin Health Company, single dose before endodontic treatment

Category

Treatment - Drugs

2

Description

Control group: Ibuprofen 400 mg tablet Saponin company single dose before endodontic treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

private dental office

Full name of responsible person

Dr Narges Hoshyari

Street address

Ghoo medical complex, gharan St, Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3331 5114

Email

narjeshoshyari@rocketmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Research and Technology Center, Moallem SQ, Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3326 1244

Email

pajoheshi@mazums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Keshvaridoost

Position

dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Tooba dental clinic, khazar Blv, Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

F.keshvaridoost@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Narges Hoshyari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tooba dental clinic, khazar Blvd, Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

narjeshoshyari@rocketmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Keshvaridoost

Position

dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Tooba dental clinic, khazar Blvd, Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

f.keshvaridoost@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available