# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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 Keshvardoost

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 11 3340 5474

**Email address**
f.keshvardoost@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 Analouge 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 Keshvardoost
**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.keshvardoost@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 Keshvardoost

**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.keshvardoost@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