Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Anahil Plus and Ibuprofen effect for pain relief after root canal treatment in patients referred to Amol private clinic - a clinical trial study

Protocol summary

Study aim

Determining the appropriate consumption pattern of Anaheal Plus for analgesic effect after root canal treatment_clinical trial

Design

A clinical trial with a control group - one-sided - randomized phase three on 90 patients

Settings and conduct

The present study was registered and implemented in Mazandaran University of Medical Sciences. The mandibular and maxillary molar teeth that suffered from irreversible pulpitis do not have periapical lesions They enter the study. The teeth are treated in two sessions Pulpectomy is performed and drugs are used between sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients 20-60 years old 2- Patients referred to Amol Dental Medical Center 3- Healthy patients in terms of systemic diseases 4- Maxillary and mandibular molar teeth, which have three canals, are included in the study 6- Teeth that have a diagnosis of irreversible periapical pulpitis and do not have periapical periodontitis Patients with preoperative pain in the moderate pain range (VAS 4-7) Exclusion criteria: 1- Patients younger than 20 years and older than 60 years 2- Consumers of any type of analgesic drug in the last 12 hours 3- Pregnant patients 4- Patients allergic to pineapple, celery, carrot, fennel, saffron and ginger5.

Intervention groups

Intervention group A Anahil Plus capsule containing 150 mg of bromelain and 300 mg of tromeric, every 8 hours for 5 days (one dose was taken one hour before treatment and after treatment every 8 hours for 5 days) Control group B, placebo drug (one dose was taken one hour before treatment and after treatment every 8 hours to 5 days) (capsule containing starch or carboxymethyl cellulose (CMC) every 8 hours to 5 days) Intervention group C received ibuprofen tablets (every eight hours for five days).

Main outcome variables

Pain intensity reported by patients based on the VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220517054898N1**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-03, 1402/06/12**
Update count: **0**

Registration date

2023-09-03, 1402/06/12

Registrant information

Name

Mohammad Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3472 8744

Email address

mamadahmadi327@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-24, 1402/06/02

Expected recruitment end date

2023-09-09, 1402/06/18

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Anahil Plus and Ibuprofen effect for pain relief after root canal treatment in patients referred to Amol private clinic - a clinical trial study

Public title
Comparison of Anahil Plus and Ibuprofen effect for pain relief after root canal treatment in patients referred to Amol private clinic - a clinical trial study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Irreversible pulpitis in three canal molar teeth Patients with pain before endo operation in the range of moderate pain (VAS 4-7) Patients with a minimum age of 20 Systemically healthy patients
Exclusion criteria:
Patients with pain before endo operation in the range of severe pain Teeth diagnosed with necrosis and periapical periodontitis Patients with severe stress and anxiety Pregnant patients
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is two-stage. In the first stage, samples with entry criteria were selected using simple random sampling method. In the second stage, block sampling method was used for random allocation. The samples were assigned to three groups using block classification. Blocking process was done with Random Allocation software. The samples were placed in 3 blocks of 30 with the mentioned method
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the drugs, double-blinding is not possible, so it is unilaterally blinded and the only person recording the pain score is blinded without knowing the type of drugs. The current study is a single-strain blinding and the Placebo group is to compare the analgesic effect with Anahil Plus.
Placebo
Used
Assignment
Other
Other design features
The maxillary and mandibular molar teeth, which have three canals and suffered from irreversible pulpitis, did not have periapical damage, and the patient expressed moderate pain intensity and anxiety level; they started studying. The teeth were worked on in two sessions, treated with pulpectomy and drugs were used between sessions.The diagnosis of irreversible pulpitis was determined according to the patients' dental history and radiological symptoms.The studied patients were randomly divided into three groups of 30 people A, B and C.Intervention group A Anahil Plus capsule containing 150 mg of bromelain and 300 mg of tromeric, Permon Amin Health Company, Tehran, Iran; every 8 hours up to 5 days (one dose was taken one hour before the treatment and every 8 hours up to 5 days after the treatment)Control group B, placebo drug (one dose was taken one hour before treatment and after treatment every 8 hours to 5 days) (capsule containing starch or carboxymethyl cellulose (CMC) every 8 hours to 5 days)Intervention group C received ibuprofen tablets (every eight hours for five days).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Khazar Blvd, Sari Faculty of dentistry (tooba dental clinic)
City
Sari
Province
Mazandaran
Postal code
4816895475
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.MAZUMS.REC.1402.153

Health conditions studied

1

Description of health condition studied
A patient with a three-channel maxilla and mandible molar tooth diagnosed with irreversible pulpitis (and the absence of periodontitis)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity reported by patients based on the VAS scale
Timepoint
Before treatment_8 hours after treatment_48 hours after treatment_5 days after treatment
Method of measurement
The method of variable measurement is VAS questionnaire, the scale of this questionnaire is classified from zero to ten. The method of using the Visual Anxiety Scale (VAS) pain questionnaire was taught to the patient. Before starting the work, the patients were asked to record the pain score before endo treatment, 8 and 48 hours and on the fifth day after endo treatment.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The studied patients are randomly divided into three groups of 30 people A, B and C.Intervention group A Anahil Plus capsule containing 150 mg bromelain and 300 mg tromeric, Permon Amin Health Company, Tehran, Iran; every 8 hours up to 5 days (one dose is taken one hour before treatment and after treatment every 8 hours up to 5 days)Infraalveolar block anesthesia is performed using 1.8 ml of 2% lidocaine with 1/80000 epinephrine (Darupakhsh, Iran). The tooth is isolated and prepared with rubber. Length determination is done with the help of periapical radiography. Cleaning and shaping is done with the help of passive preparation technique from apical to coronal. Saline and 2% hypochlorite are used as washing agents. Then the canals are dried with paper towels, calcium hydroxide and dressings are applied.The method of using the Visual Anxiety Scale or (VAS) pain questionnaire is taught to the patient. Before starting the work, patients are asked to record the pain score before endo treatment, 8 and 48 hours and on the fifth day after endo treatment.
Category
Treatment - Drugs

2

Description
Control group:Control group B, placebo drug (one dose is taken one hour before treatment and after treatment every 8 hours to 5 days) (capsule containing starch or carboxymethyl cellulose (CMC) every 8 hours to 5 days)Infraalveolar block anesthesia is performed using 1.8 ml of 2% lidocaine with 1/80000 epinephrine (Darupakhsh, Iran). The tooth is isolated and prepared with rubber. Length determination is done with the help of periapical radiography. Cleaning and shaping is done with the help of passive preparation technique from apical to coronal. Saline and 2% hypochlorite are used as washing agents. Then the canals are dried with paper towels, calcium hydroxide and dressings are applied.The method of using the Visual Anxiety Scale or (VAS) pain questionnaire is taught to the patient. Before starting the work, the patients were asked to record the pain score before endo treatment, 8 and 48 hours and on the fifth day after endo treatment.The standard treatment is the use of ibuprofen as an analgesic and pain reliever, that's why rescue dose (ibuprofen) is considered for the control group; That is, if he has pain, he can take ibuprofen and write down the number of doses taken.
Category
Treatment - Drugs

3

Description
Intervention group: Intervention group C receives ibuprofen tablets (every eight hours for five days).Infraalveolar block anesthesia is performed using 1.8 ml of 2% lidocaine with 1/80000 epinephrine (Darupakhsh, Iran). The tooth is isolated and prepared with rubber. Length determination is done with the help of periapical radiography. Cleaning and shaping is done with the help of passive preparation technique from apical to coronal. Saline and 2% hypochlorite are used as washing agents. Then the canals are dried with paper towels, calcium hydroxide and dressings are applied.The method of using the Visual Anxiety Scale or (VAS) pain questionnaire is taught to the patient. Before starting the work, patients are asked to record the pain score before endo treatment, 8 and 48 hours and on the fifth day after endo treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amol velayat clinic
Full name of responsible person
Gholam ghafari
Street address
Hezar sangar square_ emam Reza Ave_Rezvan 60
City
Amol
Province
Mazandaran
Postal code
46146437088
Phone
+98 11 4329 5310
Email
narjeshoshyari@rocketmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Narjes hoshyari
Street address
Khazar Blvd, Sari Faculty of Dentistry
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3325 4135
Email
narjeshoshyari@rocketmail.com
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
Narjes hoshyari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Khazar Blvd_Sari Faculty of dentistry
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3325 4135
Email
narjeshoshyari@rocketmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Narjes Hoshyari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Khazar Blvd, Sari Faculty of Dentistry
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3325 4135
Email
narjeshoshyari@rocketmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Narjes hoshyari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Khazar Blvd,Sari Faculty of dentistry
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3325 4135
Email
Narjeshoshyari@rocketmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document

After the completion of the project, the results will be delivered in the form of a final report and in electronic form (on a CD) to the Research Vice-Chancellor and Faculty of Dentistry of Mazandaran University of Medical Sciences

When the data will become available and for how long

The decision regarding access to the data will be the responsibility of the vice president of research and the Faculty of Dentistry of Mazandaran University of Medical Sciences, as well as the supervisor

To whom data/document is available

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

Under which criteria data/document could be used

The request should be sent to the responsible person after consultation with the research team, the data will be provided to the requesting person, and it is necessary to give reference to the data owners in the articles or wherever the data is to be used, and the use of the results only It is allowed by citing its source

From where data/document is obtainable

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

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

A written request to the vice president of research or the Faculty of Dentistry of Mazandaran University of Medical Sciences and also obtaining the consent of the supervisor

Comments