

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of preemptive ibuprofen analgesic compared to placebo on pain perception associated with the placement of temporary anchorage devices (TADs), A double blinded randomised clinical trial

Protocol summary

Study aim

Effect of preemptive ibuprofen analgesic compared to placebo on pain perception associated with the placement of temporary anchorage devices (TADs),

Design

A multicenter, randomized controlled trial, double-masked trial, parallel group.

Settings and conduct

A multicenter, randomized, double-masked trial, The Research will consist of 2 groups of 25 participants each, the medication (Ibuprofen and placebo) will be given to both groups thirty minutes before the TAD placement, 400 mg Ibuprofen (Advil, Pfizer Inc.) for the first group and placebo for the second group. Patients will be asked to fill the questionnaire form (translated SF-MPQ) and Discomfort and severity of pain will be recorded at the following times: immediately after TAD placement (T1), 1 hour after TAD placement (T2), 12 hours after TAD placement (T3), 24 hour after TAD placement (T4).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients treated with fixed orthodontic appliances 2- Patients that only need one TAD in the posterior part of the maxilla 3- Patients with minimum age of 13 years old 4- Patients that will agree to participate in the clinical trial Exclusion criteria: 1- Patients with poor oral hygiene or severe gingivitis 2- Patients with systemic diseases 3- Patients who currently are using other pain killer medications 4- Patients who are allergic to any of TAD, Ibuprofen, or Placebo medication 5- Patients who can not swallow

Intervention groups

A multicenter, randomized, double-masked trial, The Research will consist of 2 groups of 25 participants each, the medication (Ibuprofen and placebo) will be given to both groups thirty minutes before the TAD placement, 400 mg Ibuprofen (Advil, Pfizer Inc.) for the first group and placebo for the second group.

Main outcome variables

Determining severity and type of pain

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20210803052059N1**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

Arman Mohammadi Shayan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-09, 1400/11/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preemptive ibuprofen analgesic compared to placebo on pain perception associated with the placement of temporary anchorage devices (TADs), A double blinded randomised clinical trial

Public title

Effect of preemptive ibuprofen analgesic compared to placebo on pain perception associated with the placement of temporary anchorage devices (TADs), A double blinded randomised clinical trial

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients treated with fixed orthodontic appliances
Patients that only need one TAD in the posterior part of the maxilla
Patients that will agree to participate in the clinical trial

Exclusion criteria:

Patients with poor oral hygiene or severe gingivitis
Patients with systemic diseases
Patients who currently are using other pain killer medications
Patients who are allergic to any of TAD, Ibuprofen, or Placebo medication
Patients who can not swallow

AgeFrom **13 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **46****Randomization (investigator's opinion)**

Randomized

Randomization description

Each individual represents a unit in the randomization method (46 individuals = 46 units), patients are randomly allocated in to blocks thus in to one of the arms using simple random sampling by using a computer software (Randlist v1.5), the two arms in the trial were placebo group and ibuprofen group and the block size was fixed to 6 individuals per block. The seed for random generator was (1786741248), then after the list was generated allocation concealment was carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both Ibuprofen and Placebo will be packed in unclear packages and will be given to the patient by the assistance without the patient or the orthodontist

knowing which medication are in the package, for identifying the group no. 1 and 2 was written on the packages.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Central building of Tabriz medical university / gulgasht st. / Azadi st. / Tabriz

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Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.TBZMED.REC.1400.716

Health conditions studied**1****Description of health condition studied**

Malocclusion, Dental crowding.

ICD-10 code

M26

ICD-10 code description

Anomalies of dental relationship

Primary outcomes**1****Description**

Severity and type of pain during different times

Timepoint

severity and type of pain will be recorded at the following times: immediately after TAD placement (T1), 1 hour after TAD placement (T2), 12 hours after TAD placement (T3), 24 hour after TAD placement (T4).

Method of measurement

The patients will be asked to fill a questionnaire form, this form is consisted of a Persian translated copy of short form of McGill Pain questionnaire (SF-MPQ).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 participants, the medication (400 mg Ibuprofen (Advil, Pfizer Inc.)) will be given to the first groups thirty minutes before the TAD placement.

Category

Prevention

2

Description

Control group: 25 participants, the medication (Placebo) will be given to the second groups thirty minutes before the TAD placement.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences, Faculty of Dentistry

Full name of responsible person

Hezha Shafiq H. Rashid

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Dentistry faculty / Tabriz University of Medical Science / Gulgashst st. / Azadi st. / Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samie

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Grant name

Research Ethics Committees of Tabriz University of medical sciences

Grant code / Reference number

IR.TBZMED.REC.1400.716

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

1

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

Tabriz University of Medical Sciences

Full name of responsible person

Arman Mohammadi Shayan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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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