

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The study of pretreatment of alprazolam on strengthening of sedative impact of ibuprofen in patients suffering from the pain of root canal treatment.

#### Protocol summary

##### Summary

patients may experience mild, moderate to severe post endodontic pain. The aim of the present study is to investigate the role of alprazolam on the analgesic effect of Ibuprofen in post endodontic pain (PEP). The exclusion criteria are: Patients younger than 20 or older than 45 years old, Presence of systemic diseases, allergy to NSAIDs, taking sedative and other analgesics, pregnancy or breast feeding. This double-blinded randomized clinical trial will be conducted in a three day periods. The patients will be randomly allocated into control, Ibuprofen and Ibuprofen plus alprazolam groups. Fifteen patients will be entered in each group. The method is based on placebo- drug (Ibuprofen, Ibuprofen plus alprazolam) style. This study will be done in three days

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312219271N4**

Registration date: **2014-04-08, 1393/01/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-04-08, 1393/01/19

##### Registrant information

###### Name

Ali Akbar Moghadamnia

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1222 9591

###### Email address

a.moghadamnia@mubabol.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Reserch Affairs of Babol University of Medical Sciences

###### Expected recruitment start date

2012-10-26, 1391/08/05

###### Expected recruitment end date

2013-10-27, 1392/08/05

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The study of pretreatment of alprazolam on strengthening of sedative impact of ibuprofen in patients suffering from the pain of root canal treatment.

###### Public title

Alprazolam role in the analgesic effect of ibuprofen on pain after root canal therapy.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

After providing adequate information to the subjects, eligible healthy volunteer will be enrolled in the study. Inclusion criteria: be healthy; normal dite; Non-inhibitor drugs. Exclusion criteria: age below 20 and above 45; smoking; pregnancy; Breastfeeding.

###### Age

From **20 years** old to **45 years** old

###### Gender

Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **45**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Babol University of Medical Sciences

**Street address**

Ganj Afrooze Ave. University Sq.

**City**

Babol

**Postal code**

4717641376

**Approval date**

2013-07-02, 1392/04/11

**Ethics committee reference number**

2726

## Health conditions studied

### 1

#### Description of health condition studied

Pharmacokietics

**ICD-10 code**

K04.9

**ICD-10 code description**

Other and unspecified diseases of pulp and periapical tissues

## Primary outcomes

### 1

**Description**

Visual analog scale

**Timepoint**

4,6,12,24,48,72 hours after taking the medicine of regular intervals.

**Method of measurement**

Pain by visual assessment

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Control group: administration placebo one capsule daily for three days.

**Category**

Other

### 2

**Description**

Alprazolam+Ibuprofen group: administration Alprazolam+Ibuprofen(0.5mg+400mg) one capsule daily for three days.

**Category**

Treatment - Drugs

### 3

**Description**

Ibuprofen group: administration Ibuprofen 400mg one capsule daily for three days.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Ali Akbar Moghadamnia

**Street address**

Department of Pharmacology, Faculty of Medicine, Babol University of Medical Sciences

**City**

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Ganje Afrooze Ave. University SQ.

**City**

Babol

**Grant name**

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

Yes

**Title of funding source**  
Babol University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Babol University of Medical Sciences

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DR. Ali Akbar Moghadamnia

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PharmaD,phD

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*