# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The evaluation of effect of oral calcium on reducing orthodontic pain.

## Protocol summary

**Summary**

The aim of this study was to evaluate the effect of oral Calcium on reducing orthodontic pain and to compare this effect with Acetaminophen. In this clinical trial study, 40 female patients (14-19 years old) undergoing fixed orthodontic treatment, had passed at least two visits, and their pain intensity was 40-100 mm (VAS) were selected and randomly assigned to 2 groups. Psychotic status of these groups was measured with HADS (Hospital Anxiety & Depression Scale). Pain intensity before taking drug was measured with VAS (visual analogue scale). The first group took 60 calcium fort tablets (one tablet daily) and the second group took 60 Acetaminophen 325mg tablets (one tablet daily). Pain intensity was measured and compared between groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138806282481N1**
Registration date: **2010-02-19, 1388/11/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2010-02-19, 1388/11/30

**Registrant information**

**Name**
Soghra Yassaei
**Name of organization / entity**
Dental School
**Country**
Iran (Islamic Republic of)
**Phone**
+98 35 1823 8087
**Email address**
syassaei@ssu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2009-05-15, 1388/02/25

**Expected recruitment end date**

2009-09-20, 1388/06/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The evaluation of effect of oral calcium on reducing orthodontic pain.

**Public title**

The evaluation of effect of oral calcium on reducing orthodontic pain.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: female patients (14-19 years old) undergoing fixed orthodontic treatment. Having visited two times, pain intensity 40-100mm (VAS) Exclusion criteria: calcium intake in past, kidney stones, ventricular fibrillation, hypoparathyroidism

**Age**

From **14 years** old to **19 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size:

**Randomization (investigator's opinion)**

Randomized

**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee in research
**Street address**
Shahid Sadoughi University of Medical sciences and Health Services
**City**
Yazd
**Postal code**
**Approval date**
2009-04-11, 1388/01/22
**Ethics committee reference number**
4564/1/17/ب

## Health conditions studied

### 1

**Description of health condition studied**
Dentofacial anomalies
**ICD-10 code**
K07
**ICD-10 code description**
Dentofacial anomalies [including malocclusion]

## Primary outcomes

### 1

**Description**
Moderate or severe pain
**Timepoint**
90 days
**Method of measurement**
visual analogue scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
60 calcium fort tablets, one tablet daily for 2 months
**Category**
Treatment - Drugs

### 2

**Description**
60 Acetaminophen tablets, one tablet daily for 2 months
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Orthodontic clinic
**Full name of responsible person**
Soghra Yassaei
**Street address**
Atlasi Square, Shahid Ghandi Blvd.
**City**
Yazd

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Sadoughi University of Medical sciences and Health Services
**Full name of responsible person**
Soghra Yassaei
**Street address**
Bahonar Square, Sadoughi Blvd.
**City**
Yazd
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Sadoughi University of Medical sciences and Health Services
**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**
Dental School

**Full name of responsible person**
Soghra Yassaei

**Position**
Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

## 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*