

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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**Street address**

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Web page address

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