

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparative study of Calcium efficacy and placebo on leg muscle cramps during pregnancy in patients referred to clinics supervised by Bushehr University of Medical Sciences

Protocol summary

Summary

The aim of this randomized, double blind, placebo-controlled, phase 2, multicenter study is to evaluate calcium efficacy on leg muscle cramps. A total of 60 pregnant women suffering from leg cramps who sought medical treatment in three selected clinics in Bushehr were allocated into intervention or control study to receive calcium, 500mg daily for four weeks or placebo. The number and intensity of muscle cramps were evaluated and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009274824N1**

Registration date: **2011-02-05, 1389/11/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-05, 1389/11/16

Registrant information

Name

Rozita Khoramrodi

Name of organization / entity

School Of Nursing & Midwifery, Bushehr University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1455 0187

Email address

r.khoramrodi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Managment Affairs, Bushehr University Of Medical Sciences

Expected recruitment start date

2006-03-21, 1385/01/01

Expected recruitment end date

2007-11-18, 1386/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Calcium efficacy and placebo on leg muscle cramps during pregnancy in patients referred to clinics supervised by Bushehr University of Medical Sciences

Public title

Comparative study of Calcium efficacy and placebo on leg muscle cramps during pregnancy in patients referred to clinics supervised by Bushehr University of Medical Sciences

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: third trimester of pregnancy, single pregnancy, no consumption of any drug excepts for Iron and multivitamins Exclusion criteria: Irregular use of medication, PLP, unwilling to complete forms

Age

From **16 years** old to **39 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Bushehr University Of Medical Sciences

Street address

Reshehr, Sabz Abad, Bushehr

City

Bushehr

Postal code

Approval date

2006-02-28, 1384/12/09

Ethics committee reference number

2154/3/18/20/دپ

Health conditions studied

1

Description of health condition studied

leg cramp

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Leg Cramp

Timepoint

Seven days before until the end of the intervention

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 1 Placebo capsule (lactose Merk) daily for four weeks

Category

Placebo

2

Description

Intervention group: 500mg calcium, daily for four weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center Haftom Tir

Full name of responsible person

Farzaneh Noroozi- Bachelor of midwifery

Street address

Bushehr- Imam khomeini street- Boostan 19 Alley

City

BUSHEHR

2

Recruitment center

Name of recruitment center

Health center - Ali Ebn Abi Taleb

Full name of responsible person

Mahmanzar Barmshoori

Street address

Deputy for health, Bushehr University of Medical Sciences

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Managment Affairs, Bushehr University Of Medical Sciences

Full name of responsible person

Maryam Ravanipour

Street address

Bushehr University Of Medical Sciences, Reshehr, Sabzabad, Bushehr

City

Bushehr University Of Medical Science

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Research Managment Affairs, Bushehr 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**

School of Nursing and Midwifery, Bushehr University
of Medical Sciences

Full name of responsible person

Rozita Khoramrodi

Position

Master Of Midwifery

Other areas of specialty/work**Street address**

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Web page address**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