

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Vitamin D and calcium plus vitamin D for leg cramps in pregnant women: A randomised controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of Vitamin D and calcium plus vitamin D for leg cramps in pregnant women. **Design:** Triple blind Randomized Controlled Trial. **Setting and conduct:** This study will be conducted in Tabriz health centers. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 42 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. **Participants:** 126 pregnant women aged 18 to 35 years with gestational age of 25 to 30 weeks who have at least two leg cramps per week. **Interventions:** The number, severity and duration of leg cramps will be measured daily during a week before the start of the intervention. After completing the basic information and Pittsburgh sleep quality questionnaire, one intervention group will receive Vitamin D tablets (1000 units) and the other intervention group will receive calcium-vitamin D tablets (300mg calcium carbonat plus 1000 units vitamin D). The control group will receive placebo. **Main outcome measures:** Number and duration of leg cramps will be evaluated by the checklist and its severity will be assessed by VAS scale before, 4 and 8 weeks after the intervention. Secondary outcomes include sleep quality, delivery characteristics and anthropometric indicators that will be respectively assessed by Pittsburgh sleep quality index before and 8 weeks after the intervention and checklist after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040810324N12**

Registration date: **2013-05-04, 1392/02/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-30, 1392/02/10

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vitamin D and calcium plus vitamin D for leg cramps in pregnant women: A randomised controlled trial

Public title

The effect of Vitamin D and calcium plus vitamin D for leg cramps in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age of 25-30 weeks aged 18 to 35 years old; having Leg cramps at least twice a week; being literate. Exclusion criteria: Having known thyroid, cardio-vascular, diabetes or renal diseases; intake of calcium and vitamin D supplementation during pregnancy; having allergy history to studied drugs.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**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

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Postal code

00984113357311

Approval date

2013-03-14, 1391/12/24

Ethics committee reference number

91230

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

Leg cramps in pregnant women

ICD-10 code

O26.8

ICD-10 code description

Pregnancy, childbirth and the puerperium

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

The number of leg cramps

Timepoint

Before interventions, 4 and 8 weeks after intervention

Method of measurement

Daily counts

2**Description**

Severity of leg cramps

Timepoint

Before interventions, 4 and 8 weeks after intervention

Method of measurement

Visual Analog Scale (VAS)

3**Description**

Duration of leg cramps

Timepoint

Before intervention, 4 and 8 weeks after intervention

Method of measurement

According to minute

Secondary outcomes**1****Description**

Sleep quality scores

Timepoint

Before and after intervention

Method of measurement

Pittsburgh Sleep Quality Index

2**Description**

Anthropometric indices

Timepoint

After delivery

Method of measurement

Newborn growth monitoring form

3

Description

Preterm labor

Timepoint

after delivery

Method of measurement

Frequency

4

Description

Cesarean delivery

Timepoint

After delivery

Method of measurement

Frequency

Intervention groups

1

Description

The first intervention group will receive 1000 units vitamin D daily for 60 days.

Category

Treatment - Drugs

2

Description

The second intervention group will receive 300 mg carbonate calcium plus 1000 units vitamin D daily for 60 days.

Category

Treatment - Drugs

3

Description

The control group will receive 500 mg placebo tablet daily for 60 days. Placebo tablets contain aviseal, lactose and starch.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tabriz health centers

Full name of responsible person

Mansouri Ameneh

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Shakouri Seyyed Kazem

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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**

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Mansouri Ameneh

Position

MSc student in Midwifery

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mozhgan Mirghafourvand

Position

PhD of reproductive health

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

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Mirghafourvandm@tbzmed.ac.ir;

mirg1385@yahoo.com

Web page address

<http://nursing.tbzmed.ac.ir>

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