Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 envelops 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

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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 receive1000 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 avisel, 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
Nursing & Midwifery Faculty, South Shariati Street
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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

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Mirghafourvandm@tbzmed.ac.ir; mirg1385@yahoo.com

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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