

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women: a randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women

Design

A concealed, randomized, triple blind, controlled clinical trial with a parallel group design of 88 women, phase 3.

Settings and conduct

Sampling will be done in densely populated and socio-economically different centers of Malayer. Participants in the study will be assigned to two groups by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org. The allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women with gestational age of 8-10 weeks and vitamin D levels below 30 ng/ml.

Exclusion criteria: women with diabetes, thyroid and parathyroid disorders; history of macrosom neonate; body mass index above 30 kg/m² before pregnancy; pre-pregnancy polycystic ovary syndrome and history of diabetes or gestational diabetes will be excluded from the study.

Intervention groups

The intervention group will receive 4 oral tablets of vitamin D 1000 units daily and the control group will receive placebo which is quite similar in appearance to the drug used in the intervention group.

Main outcome variables

Sleep quality; pregnancy symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N61**

Registration date: **2021-01-15, 1399/10/26**

Registration timing: **prospective**

Last update: **2021-01-15, 1399/10/26**

Update count: **0**

Registration date

2021-01-15, 1399/10/26

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

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on sleep quality and pregnancy symptoms in pregnant women: a randomized controlled clinical trial

Public title

The effect of vitamin D on sleep quality and pregnancy symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant people with a gestational age of 8 -10 weeks
Vitamin D levels below 30 ng/ml

Exclusion criteria:

Women with diabetes Vitamin D levels above 30 ng/ml
Women with thyroid and parathyroid disorders according to the self-report
Women with a body mass index above 30 kg/2m before pregnancy
Women with a history of macrosomic neonate
Women with pre-pregnancy polycystic ovary syndrome, according to the self-report
Women with a history of diabetes or gestational diabetes

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be assigned to two groups (one group receiving 4,000 units of oral vitamin D daily and one group receiving placebo with the same protocol) by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

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

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-12-14, 1399/09/24

Ethics committee reference number

IR.TBZMED.REC.1399.869

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

Sleep Quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

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

Sleep quality score

Timepoint

Before the intervention and 26th week of pregnancy

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2**Description**

Pregnancy symptoms score

Timepoint

Before the intervention and 26th week of pregnancy

Method of measurement

Pregnancy Symptoms Questionnaire

Secondary outcomes

1

Description

Side effects

Timepoint

During intervention

Method of measurement

Side effects checklist

Intervention groups

1

Description

The intervention group will receive 4000 units of oral vitamin D daily produced by Dana Pharmaceutical Company, which is quite similar in appearance to the drug used in the placebo group. This intervention will last for 18 weeks.

Category

Prevention

2

Description

The control group will receive an oral placebo daily produced by Dana Pharmaceutical Company, which in terms of appearance is quite similar to the drug used in the intervention group. This study will last for 18 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Malayer city

Full name of responsible person

Zahra Mirzaee Azandaryani

Street address

Malayer city

City

Malayer

Province

Hamadan

Postal code

6578146769

Phone

+98 81 3231 2259

Email

z.mirzaee2019@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3479 6969

Email

iro@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Mirzaee Azandaryani

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3177 2048

Email

z.mirzaee2019@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3177 2048

Email

mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, South Shariati St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3177 2048

Email

mirghafourvandm@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available