Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of an additional dose of vitamin D3 supplementation on the rate of cessation and recurrence of preterm labor in women referred to the hospital

Protocol summary

Study aim
The effect of an additional dose of vitamin D3 supplementation on the rate of cessation and recurrence of preterm labor in women referred to the hospital

Design
The clinical trial has a control group, a blinded, randomized, and 4 variable blocks are used to randomly assign the samples to each of the 2 intervention and control groups.

Settings and conduct
This research is conducted in Bahlul Gonabad and Waliasr Birjand hospitals and the serum level of vitamin D of the patients was determined and the people whose serum level is less than 32 nanograms per milliliter will be included in the study. , and the intervention group will be prescribed an additional dose of 1000 units of vitamin D (2000 units in total) for a maximum of one week after the onset of symptoms of premature labor and hospitalization of the mother.

Participants/Inclusion and exclusion criteria
Vitamin D serum level less than 32 ng؛Willingness to participate in the study؛Age range 10-54 years؛Gestational age 24 to 36 weeks and 6 days؛Not having pregnancy complications؛Dilatation of less than 3 centimeters and efasman؛Absence of urinary infection and vaginal infection during pregnancy؛The unwillingness of the mother to cooperate to take a blood sample؛Mother's unwillingness to continue studying؛Occurrence of intrauterine fetal death

Intervention groups
People whose serum level is less than 32 nanograms/ml will be included in the study. The intervention group was prescribed an additional dose of 1000 units of vitamin D for a maximum of one week after the onset of premature labor symptoms and the mother was hospitalized, and then in the control group, the usual dose of 1000 units of vitamin D was prescribed daily until the end of pregnancy.

Main outcome variables
Determining the effect of an additional dose of vitamin D3 supplementation on the rate of cessation and recurrence of premature labor in women referred

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240111060683N1**
Registration date: **2024-02-12, 1402/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-12, 1402/11/23**
Update count: **0**

Registration date
2024-02-12, 1402/11/23

Registrant information

Name
somayeh khajeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 562 4250

Email address
smyhkhwajh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-10, 1402/11/21

Expected recruitment end date
2024-04-02, 1403/01/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of an additional dose of vitamin D3 supplementation on the rate of cessation and recurrence of preterm labor in women referred to the hospital

Public title
The effect of an additional dose of vitamin D3 supplementation on the rate of cessation and recurrence of preterm labor in women referred to the hospital
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Vitamin D serum level less than 32 ng Willingness to participate in the study Age range 10-54 years Gestation age 24 to 36 weeks and 6 days Not having pregnancy complications based on the mother's statement or information in the mother's file (multiple twins, polyhydramnios, preeclampsia, uncontrolled diabetes, uncontrolled hypothyroidism) that causes premature birth. No rupture of the water bag Dilatation of less than 3 centimeters and defecation Failure to perform cerclage and history of cerclage Absence of urinary infection and vaginal infection during pregnancy based on the mother's statement or the information in the mother's file
Exclusion criteria:
The mother's unwillingness to cooperate to take a blood sample Mother's unwillingness to continue studying Occurrence of intrauterine fetal death
Age
From **10 years** old to **56 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be non-random (available) and for random allocation of samples to each of the 2 intervention and control groups, blocks of 4 variables will be used. In this way, first 6 possible states of blocks (BAAB, ABBA, BABA, BBAA, ABAB, AABB) are listed and a number from 1 to 6 is assigned to each block. Then, a number between 1 and 6 is randomly selected and then people are assigned to the vitamin D (B) supplement group and the control group (A) based on the block corresponding to the selected number. This work continues until the sample volume is completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding in this study is the person who conducts the vitamin D level test, because she does not know which group she is conducting the test.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی گناباد
Street address
Motahari, Motahari 9
City
Birjand
Province
South Khorasan
Postal code
9719664971
Approval date
2024-01-07, 1402/10/17
Ethics committee reference number
IR.GMU.REC.1402.134

Health conditions studied

1

Description of health condition studied
The effect of an additional dose of vitamin D3 supplement on the rate of cessation and recurrence of premature labor in women referred to Bahlul Gonabad and Vali Asrbirjand hospitals 1402
ICD-10 code
O60
ICD-10 code description
Preterm labor

Primary outcomes

1

Description
The number of people who gave birth prematurely (before 37 weeks of pregnancy).
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Follow-up of mothers and that their delivery was in

several weeks of pregnancy

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, an additional dose of 1000 units of vitamin D (2000 units in total) will be prescribed to the intervention group for a maximum of one week after the onset of premature labor symptoms and hospitalization of the mother. It should be noted that the usual dose of 1000 units of vitamin D is prescribed until the end of The pregnancy period will continue. Vitamin D consumption substance, its chemical composition is vitamin D3 (calciferol bag), mothers consume 1000 units of vitamin D3 for one week. And its manufacturing plant in Iran is the holder of the manufacturing license of Hakiman Teb Kar Company

Category
Prevention

2

Description
Control group: The usual dose of 1000 units of vitamin D per day will be prescribed until the end of pregnancy

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr Birjand Hospital

Full name of responsible person
Somayeh Khajesh

Street address
South Khorasan, Birjand, Ghafari St., Zakariya Razi St., in front of the University of Medical Sciences

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۹۶۴۱۵۱

Phone
+98 56 3162 2001

Email
valiasr@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Dr. Lily Sadegh Moghadam

Street address
Khorasan Razavi - Gonabad, near the Asian road, Research and Technology Vice-Chancellor of Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Email
ls.moghadam@gmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
Somayeh Khajeh

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Motahari 9, Plak 7

City
Birjand

Province
South Khorasan

Postal code
971966471

Phone
+98 915 562 4250

Email
smyhkhwajh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Somayeh Khajeh

Position
Midwifery master's student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Motahari, Motahari 9 plate 7

City
Birjand

Province
South Khorasan

Postal code
9719664971

Phone
+98 915 562 4250

Email
smyhkhwajh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Somayeh Khajeh

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Motahari, Motahari 9 plate 7

City
Birjand

Province
South Khorasan

Postal code
9719664971

Phone
+98 915 562 4250

Email
smyhkhwajh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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

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

Title and more details about the data/document
I would like to share some data

When the data will become available and for how long
I do not set a time frame

To whom data/document is available
I haven't made a decision on this yet

Under which criteria data/document could be used
I haven't made a decision on this yet

From where data/document is obtainable
Refer to the email address

What processes are involved for a request to access data/document
Refer to the email address

Comments