

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Vitamin D supplementation on fetal antropometric parameters in pregnant ladies

Protocol summary

Study aim

Determination of the effect of vit D supplementation on fetal anthropometric parameters

Design

In this research 130 patients referring to perinatal clinic were chosen. After informed consent and posture pregnancy test, concomitant with first trimester routine test, Blood sample would be freezed at -80 to determination Vit D level after finishing the research. Then patients were randomly divided into two control & intervention groups by SPSS & code was allocated to each one of them.

Settings and conduct

After random division into case and control group , The intervention group also receives routine gestational medications such as calcium and 1000 unit of vitamin D per day. At 12, 19, and 34, ultrasound is used to measure variables. Then the level of vitamin D in the frozen sample is checked for all patients. They are interpreted in terms of results are classified in three group deficiency, insufficiency, sufficient in terms of vitamin D levels. The patient, a statistician and a sonologist will be unaware of all the results until the final conclusion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian race; Healthy appearance; No history of chronic disease; Normal body mass; non smoker Exclusion criteria: Abortion; Intrauterine fetal death; multi fetal pregnancy pregnancy with abnormal fetus

Intervention groups

The control group received routine pregnancy care including calcium and case group received 1000 unit of vitamin D per day.

Main outcome variables

Fetal anthropometric parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140317017034N6**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **retrospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Homeira Vafaei Cisakht

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

vafaeih@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vitamin D supplementation on fetal antropometric parameters in pregnant ladies

Public title

Effect of Vitamin D in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian race Healthy appearance No history of chronic disease Normal body mass non smoker

Exclusion criteria:

Abortion Intrauterine fetal death Multiple pregnancy pregnancy with abnormal fetus

Age

From **20 years** old to **34 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Permutation block method, they are divided into control and intervention groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City

Shiraz

Province

Fars

Postal code

34786-71946

Approval date

2017-10-21, 1396/07/29

Ethics committee reference number

IR.SUMS.MED.REC.1396.78

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

Supplements in pregnancy

ICD-10 code

F51.0

ICD-10 code description

maternal disorders predominantly related to pregnancy

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

Femur length

Timepoint

12th, 19th and 34th weeks of pregnancy

Method of measurement

Ultrasound machine

2**Description**

CRL

Timepoint

12th, 19th and 34th weeks of pregnancy

Method of measurement

Ultrasound machine

3**Description**

PMD, MSD, HL , fetal weigth

Timepoint

12th, 19th and 34th weeks of pregnancy

Method of measurement

Ultrasound machine

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Vit D 1000 unit per day until delivery.

Category

Treatment - Other

2**Description**

Control group: Routine pregnancy care including calcium

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Niloofar Namazi

Street address

Shahid Chamran blvd, Hafez Clinic

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hafez_perina@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Baser Hashemi

Street address

Building of Shiraz University of Medical Sciences,
Zand Ave

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hashemib@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shiraz University Of medical Science

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

Shiraz University of Medical Sciences

Full name of responsible person

Niloofar Namazi

Position

Resident of obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Department of obstetrics and gynecology, Shahid
Faghihi Hospital, Zand St, Shiraz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Homeira Vafaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Bazrafshan

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Laboratory Medicine

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Maternal-fetal medicine Research Center, Shiraz
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bazrafshan.kh@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

IPD: 2018 Ethic form: 2018

To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: OB & Gyn ward Shiraz university of medical sciences
Ethic form: OB & Gyn ward Shiraz university of medical sciences

What processes are involved for a request to access data/document

IPD: Vice chancellery Ethic form: Vice chancellery

Comments