

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of sun exposure versus vitamin D supplementation for pregnant women with vitamin D deficiency

Protocol summary

Summary

The aim of this study is to evaluate the effect of sun exposure versus vitamin D supplementation for pregnant women with vitamin D deficiency. This double-blind prospective clinical trial will be performed on 80 pregnant women with vitamin D deficiency, patients whom will have improper use of vitamin D, inappropriate exposure to sunlight, preterm labor, having dark skin and lose to follow-up due to various causes, must exit from the study. Group A will be treated with vitamin D 4,000 IU per day for 10 weeks, while group B will be recommended for sun exposure for 30 minutes daily ((from shoulder to fingers and from femur to toes) 30% body surface area) for 10 weeks in summer and between 10 am to 4 pm in direct sunlight. At birth, 25-hydroxyvitamin D3 serum level will be measured in mothers and will be compared with previous one. In addition, head circumference, weight and height of infants in both groups, will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101227998N2**

Registration date: **2016-12-15, 1395/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-15, 1395/09/25

Registrant information

Name

Maryam Hajjhashemi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 6578

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Isfahan university of Medical Science

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sun exposure versus vitamin D supplementation for pregnant women with vitamin D deficiency

Public title

Comparison of sun exposure versus vitamin D supplementation for pregnant women with vitamin D deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Patients who want to cooperate in study and consent to participate in the study; having gestational age 14 to 18 weeks; (serum levels of 25-hydroxyvitamin D3 <30 ngr/ml); single fetus; no history of chronic hypertension, chronic diseases such as musculoskeletal, diabetes, parathyroid, hepatitis, kidney

and any kind of malabsorption disorders, skin disease, skin cancer; living in the Isfahan. Exclusion criteria withdrawal of the study; improper use of vitamin D; inappropriate exposure to sunlight; preterm labor; having dark skin and loss to follow-up due to various causes.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomized number table

Secondary Ids

empty

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

Ethics committee of University of Isfahan Medical Sciences

Street address

Isfahan, Hezar jarib street, Isfahan university

City

Isfahan

Postal code**Approval date**

2014-09-23, 1393/07/01

Ethics committee reference number

394132

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

vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

vitamin D deficiency , unspecified

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

Serum vitamin D level

Timepoint

Pregnant women with gestational age 14 - 18 weeks and after 10 week using medicine or exposure to sunlight

Method of measurement

Serum analysis (nanogram)

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

Infant head circumference

Timepoint

at birth

Method of measurement

standard meter

2**Description**

hieght of newborn

Timepoint

At birth

Method of measurement

Standard meter

3**Description**

Infant weight

Timepoint

At birth

Method of measurement

Standard scale

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

Intervention group: will be recommended for sun exposure for 30 minutes daily (from shoulder to fingers and from thigh to toe (30% body surface area) without use of sunscreen) for 10 weeks in summer and between 10 am to 4 pm in direct sunlight

Category

Prevention

2**Description**

Control group:will be receive 4 tabs each one include 1000 IU of vitamin D manufactured by Iranian Zahravi Co. per day for 10 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Obstetrics of Beheshti hospital

Full name of responsible person

Azadeh Khorsandi, resident

Street address

Pole Felezy street

City

Isfahan

2

Recruitment center

Name of recruitment center

Department of Obstetrics of Alzahra hospital

Full name of responsible person

Azadeh Khorsandi-resident

Street address

Shohadaye-Sofhe street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr.Amir Rahimi

Street address

Hezar Jarib street

City

Isfahan

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 of Isfahan 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

Isfahan department of medicin

Full name of responsible person

Azadeh Khorsandi

Position

resident

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Beheshti hospital

Full name of responsible person

Maryam Hajihashemi

Position

Gynecologist

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Resident

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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