

Differences between sun exposure and vitamin D supplementation on blood pressure of pregnant women and size of newborn babies

Submission date 27/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/02/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2022	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Vitamin D helps regulate the amount of calcium and phosphate in the body. These nutrients are needed to keep bones, teeth, and muscles healthy.

Vitamin D deficiency in pregnant women is a global health problem in tropical and subtropical countries. This is caused by lack of sun exposure, vitamin D supplementation, and intake of foods containing vitamin D.

Who can participate?

Participants in this study are pregnant women with 20 weeks duration of pregnancy.

What does the study involve?

Participants will have a 25(OH)D examination to know the level of vitamin D, a blood pressure measurement, and a discussion related to pregnancy.

What are the possible benefits and risks of participating?

Benefits: potential health benefit from improved vitamin D intake

Risks: discomfort when having blood taken

Where is the study run from?

Diponegoro University (Indonesia)

When is the study starting and how long is it expected to run for?

March 2021 to May 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Rita Sunarno, sunarno_rita@yahoo.co.id

Contact information

Type(s)

Principal investigator

Contact name

Mrs Rita Sunarno

ORCID ID

<https://orcid.org/0000-0002-9377-582X>

Contact details

Public Health Diponegoro University

Prof.Soedarto Street, No. 1269

Tembalang

Semarang

Indonesia

50275

+62 8155614633

sunarno_rita@yahoo.co.id

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Differences in the effect of sun exposure and vitamin D supplementation on blood pressure of pregnant women and anthropometric status of newborn babies

Study objectives

There are differences in the effect of sun exposure and vitamin D supplementation on blood pressure of pregnant women and anthropometric status of newborn babies

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/05/2021, Health Research Ethics Committee Faculty of Public Health Diponegoro University (Prof Soedarto No 1269, Tembalang, Semarang 50275, Indonesia; +62 247460044, fkm@undip.ac.id), ref: 165/EA/KEPK-FKM/2021

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of vitamin D deficiency in pregnant women

Interventions

Participants are randomly divided into three groups using a computerized random number. Group 1 receives standard therapy (Calcium, Fe) plus sun exposure three times every week for 15 - 30 minutes.

Group 2 receives standard therapy (Calcium, Fe) plus vitamin D supplementation 1000 IU/day. Group 3 (control group) receives standard therapy (Calcium, Fe).

The intervention starts from 20 weeks gestation. The duration of the intervention is 17 weeks. Every group has 25(OH)D examination before and after the intervention. Each group has a blood pressure examination before intervention and every three weeks. Anthropometric status of the newborn is measured at delivery.

Intervention Type

Supplement

Primary outcome(s)

25(OH)D is measured using ELFA method before and after intervention

Key secondary outcome(s)

1. Blood pressure is measured using a tensimeter before intervention and every three weeks
2. Anthropometry of the newborn is measured using weighing scale and microtoise at delivery

Completion date

31/05/2022

Eligibility**Key inclusion criteria**

1. Pregnant women with 20 weeks gestation
2. 25(OH)D less than 30 ng/mL

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

120

Key exclusion criteria

1. Blood pressure more than 140/90 mmHg
2. Having diabetes therapy
3. Consumed vitamin D supplementation

Date of first enrolment

01/08/2021

Date of final enrolment

31/01/2022

Locations

Countries of recruitment

Indonesia

Study participating centre

Public Health Services in Indonesia

Prof. Soedarto SH street

Tembalang

Semarang

Indonesia

50275

Sponsor information

Organisation

Diponegoro University

ROR

<https://ror.org/056bjta22>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date