ISRCTN87262826 https://doi.org/10.1186/ISRCTN87262826

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

Registration date
03/02/2022

Overall study status
Completed

Last Edited
31/01/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
http://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures
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

Overall study start date
15/03/2021

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

Age group
Adult

Sex
Female

Target number of participants
108, each group consist of 36 participants

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

Sponsor details
Prof. Soedarto SH street, number 1269
Tembalang
Semarang
Indonesia
50275
+62 247460020
dkm@live.undip.ac.id

Sponsor type
University/education

Website
http://www.fkm.undip.ac.id

ROR
https://ror.org/056bjta22

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2022

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