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Prevention of pre-eclampsia through vitamin D supplementation: a single-blinded randomized clinical trial without placebo

Submission date
11/11/2020

Recruitment status
No longer recruiting

Registration date
17/11/2020

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pre-eclampsia is a condition that causes high blood pressure during pregnancy and after labour. It is the third highest cause of maternal death in the world. Vitamin D supplementation can counteract the changes in the placenta that cause the clinical symptoms of pre-eclampsia. The aim of this study is to evaluate the benefits of this supplement.

Who can participate?
Women who are pregnant for the first time

What does the study involve?
Participants are randomly allocated to one of two groups. The supplement group takes vitamin D by mouth as one dose per month from the 3rd to the 8th month of pregnancy. The control group will be followed in the antenatal clinic and will receive an iron supplement and anti-parasitic treatment. Blood samples will be collected at the start and the end of the study to measure vitamin D and calcium.

What are the possible benefits and risks of participating?
The participants may benefit from the reputed effects of vitamin D. The possible risks include side effects of vitamin D.

Where is the study run from?
University of Lubumbashi (Congo, Democratic Republic)

When is the study starting and how long is it expected to run for?
May 2017 to August 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Richard Kabuyanga Kabuseba
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Pre-eclampsia in Kivu: vitamin D levels and impacts of vitamin D supplementation on obstetric-neonatal outcomes in primigravida

Study objectives
Supplementation of pregnant women with vitamin D improves the health of primigravida (potentially at risk of preeclampsia) and the fetus safely.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/02/2019, Ethics Committee of the University of Lubumbashi (B.P: 1825 Lubumbashi, Democratic Republic of Congo; +243 (0)995258703, +243 (0)997022438; clubabankulu2017@gmail.com, gabybora2003@yahoo.fr, Eth_med@yahoo.fr), ref: UNILU/CEM /125/2019

Study design
Single-blinded randomized clinical trial without placebo

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
Patients will be divided into two groups based on gestational age (randomized into two groups).

Supplemented group: 60,000 IU of VITOSSAMIN® D3 (cholecalciferol) orally in one dose per month from the 3rd (≤15 weeks of amenorrhoea) to the 8th month of pregnancy, i.e. 360,000 IU in total.
Control group: does not receive a placebo but will be followed in the ANC and will receive an iron supplement and anti-parasitic treatment. These are primigravidae recruited with a pregnancy age exceeding 15 weeks during the recruitment period and not having completed the second trimester.

Blood will be collected at the recruitment stage and at the end of the trial to measure vitamin D and calcium. Laboratory monitoring will be performed twice at the 7th month and at the delivery.

Selection and recruitment visit: During the 3rd month visit between 11 and 14 weeks supplemented pregnant women will be identified and their informed consent (written) obtained. Non-supplemented pregnant women are also selected during the ANC.

Visits: The patients will be followed every month during the normal pregnancy follow-up (PNC)
End of study visit: after the 34th week of pregnancy a blood sample will be collected for maternal and neonatal indicators.

Intervention Type
Supplement

Primary outcome measure
Percentage of patients with preeclampsia during pregnancy, evidenced by the occurrence of hypertension (systolic blood pressure [SBP] greater than or equal to 140 mmHg and/or diastolic blood pressure [DBP] greater than or equal to 90 mmHg, taken twice 4-6 hours apart, at rest) and 2 x proteinuria after 20 weeks of amenorrhoea

Secondary outcome measures
For the patients:
1. Gestational age for any incident and for preeclampsia, measured during antenatal care or other consultations by taking blood pressure, albuminuria measurement to confirm preeclampsia from recruitment (enrollment) to postpartum
2. Other clinical signs: given the atypical forms of preeclampsia, some clinical signs according to ACOG may allow the diagnosis of preeclampsia in the absence of proteinuria. The occurrence of these signs is monitored from the time of enrolment until delivery by means of an anamnesis, clinical and laboratory examination, and the pregnant woman is monitoring the antenatal care, of which she is aware
3. Incidents (eclampsia, detachment of the normally inserted placenta, maternal death) measured according to clinical, paraclinical (ultrasound and biology) examination from enrolment to postpartum (or death)
4. Serum concentration of 25OH-D, measured using iChroma II analyser (Boditech Med Inc, South Korea), at enrollment when the pregnant woman is carrying a pregnancy of age ≤14 weeks of amenorrhoea for the gestates to be supplemented and between 34 weeks of amenorrhoea and delivery (thus two samples for each subject), and for the other group after 14 weeks of amenorrhoea and between 34 weeks of amenorrhea and delivery

In newborns:
1. Birth weight measured using scale at birth
2. Height measured using scale at birth
3. Cranial perimeter measured by tape measure by taking the circumference of the head through the glabella just after delivery
4. Intrauterine growth retardation noted at birth but detected by ultrasound as the pregnant woman is following ANC. Confirmation is done at birth with the use of tables
5. Death in utero observed after inclusion in the cohort (as it can occur at any time) and diagnosed by ultrasound before birth

Overall study start date
01/05/2017

Completion date
31/08/2021

Eligibility

Key inclusion criteria
Primipara, monoembryonic pregnancy (≤15 weeks of amenorrhoea for pregnant women to be supplemented)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
672

Total final enrolment
1232

Key exclusion criteria
1. IMC <17 and ≥ 30 but before pregnancy
2. Pregnant women suffering from calcium urinary lithiasis, renal failure, poorly controlled hypertension, unbalanced diabetes (fasting blood sugar >7 mmol/l or blood sugar >11 mmol/l), hypercalcemia (>2.65 mmol/l) and other phosphocalcic pathologies, bone diseases, lithium intake, digestive malabsorption

Date of first enrolment
01/03/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
Hopital Provincial Du Nord-Kivu
Congo, Democratic Republic
-

Study participating centre
Hgr Charite Maternelle
Congo, Democratic Republic
-

Study participating centre
Hopital De Panzi
Congo, Democratic Republic
-

Study participating centre
Hopital De Kyeshero
Congo, Democratic Republic
-

Study participating centre
Hopital Heal Africa
Congo, Democratic Republic
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Study participating centre
Hopital De Mwesso
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Sponsor information

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Sponsor type

University/education

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ROR
https://ror.org/01mn7k054

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The protocol will be available at the end of the study when the results are published. It is not yet available online.

The final research report will be written in collaboration with the aforementioned management team. The biostatistician will be interested in the required analyzes. The final version must be endorsed by the signature of each member of the team as soon as possible after the actual end of the research. The study report will be submitted to the relevant competent authorities when this research is launched.

The principal investigator remains the owner of the data and no use or transmission to a third party can be made without his prior consent. The results will be made public regardless of their trend.

The first signatories of the publications will be the people who actually participated in the development of the protocol and its progress as well as in the drafting of the results.

Intention to publish date
28/02/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request at the end of the study according to the sharing policy of the university. The researchers will treat this data in strict anonymity when it is published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/02/2024	09/02/2024	Yes	No