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Vitamins in Preeclampsia (VIP): a multicentre randomised clinical trial of vitamin C and E supplementation in pregnancy for the prevention of pre-eclampsia (India, Peru, Vietnam)

Submission date
06/06/2005

Registration date
07/06/2005

Last Edited
25/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/A35048

Study information

Scientific Title

Study objectives
The specific aim of the proposed study is to determine whether administration of 1000 mg of vitamin C and 400 iu of vitamin E, from the second trimester, to high risk women, is associated with a reduction in the incidence of preeclampsia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the World Health Organization (WHO) Scientific and Ethical Review Board and Ethical Review Committee in 2004; renewed approval in 2006.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Randomised to Vitamin C (1000 mg) and Vitamin E (400 IU), or placebo to be taken daily until delivery.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin C and Vitamin E

Primary outcome measure
Occurrence of pre-eclampsia: defined as gestational, severe gestational hypertension and proteinuria:
1. Gestational hypertension will be defined as two or more readings of diastolic blood pressure greater than or equal to 90 mmHg (using Korotkoff V) taken more than or equal to 4 hours, but less than 168 hours apart, and occurring after 20 weeks of pregnancy or in the early postnatal period, and excluding labour
2. Severe gestational hypertension will be defined as two recordings of diastolic blood pressure of 110 mmHg or higher at least 4 hours apart, (but less than 168 hours apart) or one recording of diastolic blood pressure greater than 120 mmHg
3. Proteinuria will be defined as excretion of greater than 300 mg protein in 24 hours or 2 readings of greater than or equal to 1+ on dipstick of Mid-Stream Urine (MSU)/Catheter Specimen Urine (CSU) where 24 hour collection is not available

Secondary outcome measures
1. Pre-eclampsia as defined in the context of the WHO calcium supplementation trial:
Pre-eclampsia is defined as hypertension associated with proteinuria. Hypertension is defined as blood pressure greater than or equal to 140 mmHg systolic and/or 90 mmHg diastolic occurring in two occasions at least four hours to a week apart after the 20th week of pregnancy. Diastolic blood pressure will be measured at the 5th Korotkoff sound, which is the disappearance of the sounds. Proteiunuria is defined if protein in urine is greater than or equal to 300 mg in 24 hours urine specimen or corresponding level of 1+ or more on dipstick.
2. Principal neonatal outcomes:
2.1. Death, intrauterine or neonatal before discharge from the hospital
2.2. Low birthweight, defined as below 2.5kg
2.3. Small for gestational age as defined by WHO guidelines: infants below the 10th percentile of the birth-weight-for-gestational age, sex specific, single/twins curve
3. Other secondary outcome measures (also adequately powered to detect important effects):
3.1. Preterm birth (before 37+0 weeks)
3.2. Use of health care resources: antenatal inpatient days
3.3. Gestational age at delivery

Overall study start date
27/07/2004

Completion date
27/07/2006

Eligibility

Key inclusion criteria
14^+0 - 21^+6 weeks pregnant women with one or more of the following risk factors:
1. Chronic hypertension - diastolic Blood Pressure (BP) greater than 90 mmHg
2. Pre-gestational diabetes
3. Arterial, venous or small vessel thrombosis in any organ tissue
4. Unexplained death of morphologically normal foetus at or beyond ten weeks gestation
5. Premature births before 34 weeks due to pre-eclampsia, eclampsia or severe placental insufficiency

6. Unexplained consecutive spontaneous abortions before ten weeks
7. Chronic renal disease
8. Multiple pregnancy
9. Past history of pre-eclampsia, eclampsia, HELLP syndrome (Haemolysis, Elevated Liver enzyme Levels and low Platelet count)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1790

Key exclusion criteria
1. Inability to give informed consent
2. Women taking supplements containing greater than 200 mg vitamin C or greater than 50 IU vitamin E daily dose
3. Women taking warfarin

Date of first enrolment
27/07/2004

Date of final enrolment
27/07/2006

Locations

Countries of recruitment
India

Peru

Switzerland

Viet Nam

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

Sponsor details
20 Avenue Appia
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Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA) /World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration