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A randomised controlled trial of vitamin C and E supplementation to prevent pre-eclampsia in women at risk

Submission date	Recruitment status	[_] Prospectively registered
08/10/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/11/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2015	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.medscinet.com/vip/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of vitamin C and E supplementation to prevent pre-eclampsia in women at risk

Acronym
VIP - The Vitamins In Pre-eclampsia Trial

Study objectives
A small study undertaken by the research team at St Thomas' Hospital in London, suggested that vitamins may help prevent pre-eclampsia. We asked a group of pregnant women, known to be at high risk of developing pre-eclampsia, to take vitamin C and vitamin E, or placebos (dummy tablets) from about 16 weeks of pregnancy until they had their babies. Neither the women nor the researchers knew who had the vitamins and who had the look alike tablets. We found that the women who had the vitamins were less likely to develop pre-eclampsia. However this was a very small project, and it is important that we know for certain whether these vitamins help protect women from pre-eclampsia, without causing any harm to the baby.

The hypothesis of this trial is:
Does antioxidant supplementation prevent the incidence of pre-eclampsia in women with identified risk factors?

Please note that the anticipated end date of this trial was brought forward to 01/12/2005.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Patient information can be found on the website at: http://www.medscinet.com/vip/

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

Interventions
Vitamin C 1000mg and vitamin E 400IU or placebo daily from recruitment (14-22 weeks gestation) until delivery.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin C 1000mg and vitamin E 400IU

Primary outcome measure
1. Incidence of pre-eclampsia
2. Birthweight

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Women with identified additional risk factors for pre-eclampsia in ten geographical areas, and 22 hospitals through England:
1. Pregnant women between 14 and 22 weeks' gestation
2. A history of pre-eclampsia (requiring delivery less than 37 weeks) in preceding pregnancy, eclampsia or Haemolysis, Elevated Liver enzyme levels and Low Platelet count (HELLP) syndrome (at any time)
3. Women with essential hypertension, diabetes (requiring treatment), Systemic Lupus Erythrematosus (SLE)/Anti-Phospholipid antibody Syndrome (APS) with renal imvolvement
4. In the current pregnancy: abnormal uterine artery Dopplers (18 to 22 weeks), multiple pregnancy, diastolic Blood Pressure (BP) more than 90 mmHg (before 20 weeks)
5. Primparous women with Body Mass Index (BMI) more than 30

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2400

Key exclusion criteria
1. Inability/unwillingness to give informed consent
2. Women taking warfarin (due to the theoretical potentiation of warfarin by Vitamin E)

Date of first enrolment
01/08/2003

Date of final enrolment
29/04/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
The Guy's, King's and St Thomas' Hospitals' Medical and Dental School
James Clerk Maxwell Building
57 Waterloo Road
London

England
United Kingdom
SE1 8WA

Sponsor type
Hospital/treatment centre

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (grant ref: ALPOSTON 069056)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/04/2006		Yes	No