

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

Submission date 08/10/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/11/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/06/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

1. Incidence of pre-eclampsia
2. Birthweight

Key secondary outcome(s)

No secondary outcome measures

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 Erythematosus (SLE)/Anti-Phospholipid antibody Syndrome (APS) with renal involvement
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. Primiparous women with Body Mass Index (BMI) more than 30

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre

St Thomas' Hospital

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

King's College London (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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes