

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

<b>Submission date</b> 08/10/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/11/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> 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

## Study website

<http://www.medscinet.com/vip/>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Lucilla Poston

### Contact details

Division of Reproduction, Endocrinology & Diabetes  
10th Floor North Wing  
St Thomas' Hospital  
Lambeth Palace Road  
London  
United Kingdom  
SE1 7EH  
+44 (0)20 7188 3641  
[lucilla.poston@kcl.ac.uk](mailto:lucilla.poston@kcl.ac.uk)

## 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 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

**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?
<a href="#">Results article</a>	results	08/04/2006		Yes	No