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The effect of antioxidant supplementation on women with threatened miscarriage

Submission date 29/04/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/06/2004	**Overall study status** Completed	
Last Edited 24/05/2016	**Condition category** Pregnancy and Childbirth	

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
03/0265

Study information

Scientific Title

The effect of antioxidant supplementation on women with threatened miscarriage

Acronym
TMT (Threatened Miscarriage Trial)

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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

Health condition(s) or problem(s) studied
Threatened Miscarriage

Interventions
Intervention: Vitamin C 1000 mg and Vitamin E 400 IU
Control: Placebo

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure

Incidence of miscarriage, late miscarriage and pre-term labour.

Secondary outcome measures
Incidence of pre-term pre-labour rupture of the membranes, fetal growth restriction and pre-eclampsia.

Overall study start date
01/03/2004

Completion date
28/02/2006

Eligibility

Key inclusion criteria
Women who present with first trimester bleeding

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
580

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2004

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Obstetrics & Gynaecology
London

United Kingdom
WC1E 6HX

Sponsor information

Organisation
University College London Hospitals NHS Trust (UK)

Sponsor details
UCLH/UCL Research & Development Governance Committee
Research and Development Directorate
University College London Hospitals NHS Trust
1st Floor, Maple House
149 Tottenham Court Road
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Government

Funder Name
The Early Pregnancy Research Fund (0125), University College London Hospital (UK)

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