The effect of vitamin C and E supplementation in women with a history of two early pregnancy failures - a randomised controlled trial

| Submission date 29/04/2004 | Recruitment status Stopped | Prospectively registeredProtocol |
|--------------------------------------|--------------------------------------|---|
| Registration date | Overall study status | Statistical analysis plan |
| 04/06/2004 | Stopped | Results |
| Last Edited | Condition category | Individual participant data |
| 27/11/2013 | Pregnancy and Childbirth | Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Eric Jauniaux

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

03/0061

Study information

Scientific Title

Acronym

AIM (Antioxidants in Miscarriage)

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

Health condition(s) or problem(s) studied

Miscarriage

Interventions

Intervention: Vitamin C 1000 mg and Vitamin E 400 IU

Control: Placebo

Updated 27/11/2013: the trial was stopped in October 2009 due to poor recruitment and lack of funding.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2000

Completion date

31/05/2001

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Women with a history of two or more early pregnancy losses, with no identifiable cause for the losses

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2000

Date of final enrolment

31/05/2001

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

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 London United Kingdom W1P 9LL

Sponsor type

Not defined

ROR

https://ror.org/042fqyp44

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Early Pregnancy Research Fund (0125). University College London Hospital.

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 summaryNot provided at time of registration