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Australasian Collaborative Trial of Vitamin C and Vitamin E supplementation for the prevention of pre-eclampsia

Submission date 18/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2005	**Overall study status** Completed	
Last Edited 27/01/2011	**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

N/A

Study information

Scientific Title

Acronym
ACTS

Study objectives
Primary hypotheses:
The primary hypotheses of the study are that vitamin C and E supplementation from 14 weeks gestation in nulliparous women:
1. Reduces the incidence of small for gestational age infants
2. Reduces the incidence of clinical pre-eclampsia
3. Reduces the risk of death or serious adverse outcome for the infant

Secondary hypothesis:
The secondary hypothesis is that vitamin C and E supplementation from 14 weeks gestation in nulliparous women reduces the risks of adverse outcomes for the woman up to six weeks postpartum.

Please note that the target number of participants was added as of 10/09/2007.

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)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Pre-eclampsia
Intrauterine growth restriction

Interventions
Vitamin C (1000 mg) and Vitamin E (400 IU) daily compared with placebo

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure
1. Incidence of small for gestational age infants
2. Clinical pre-eclampsia
3. Death or serious adverse pregnancy outcome for the infant

Secondary outcome measures
Severe adverse outcomes for the woman up to six weeks postpartum.

Overall study start date
01/12/2001

Completion date
31/01/2005

Eligibility

Key inclusion criteria
All nulliparous women presenting to the antenatal clinic at the collaborating centre with a singleton pregnancy, between 14-22 weeks gestation, a normal blood pressure, and expected to give birth at the collaborating centre. Informed, written consent is necessary and there must be no contraindication to vitamin C or E therapy.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1877

Key exclusion criteria
Women with any of the following: multiple pregnancy, life threatening fetal anomaly on ultrasound, known thrombophilia, chronic renal failure, hemochromatosis, women on heparin, warfarin or antihypertensive therapy.

Date of first enrolment
01/12/2001

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
Australia

Study participating centre
University of Adelaide
North Adelaide
Australia
5006

Sponsor information

Organisation
The University of Adelaide (Australia)

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Sponsor type
University/education

ROR
https://ror.org/00892tw58

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council 207744

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	27/04/2006		Yes	No
Results article	results	30/07/2008		Yes	No
Results article	results	17/09/2010		Yes	No