

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	<input type="checkbox"/> Prospectively registered
Registration date 17/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2011	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

Prof Caroline Crowther

Contact details

University of Adelaide
Women's & Children's Hospital
72 King William Road
North Adelaide
Australia
5006
+61 (0)8 8161 7647
caroline.crowther@adelaide.edu.au

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/00892tw58>

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council 207744

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