

International Trial of Antioxidant for the Prevention of Preeclampsia

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/09/2025	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

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Additional identifiers

Protocol serial number
MCT-62005

Study information

Scientific Title

Antioxidants for the prevention of preeclampsia: a randomised controlled trial

Acronym

INTAPP

Study objectives

To determine whether daily supplementation of vitamin C and vitamin E reduce the incidence of gestational hypertension (with or without proteinuria) and its adverse conditions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Centre De Recherche De L'Hopital Sainte-Justine, Comité d'éthique de la recherche gave approval on the 1st December 2003.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gestational hypertension with or without proteinuria (preeclampsia)

Interventions

Group One (Experimental): Daily supplementation with 1 g Vitamin C, 400 IU Vitamin E

Group Two (Control): Matching placebo

The duration of the follow-up varies for each participant. The woman is randomised between 12^{0/7} to 18^{6/7} weeks of pregnancy and she takes the medication daily until the date of delivery.

Trial details received: 12 Sept 2005

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vitamin C, vitamin E

Primary outcome(s)

Gestational hypertension, with or without proteinuria and adverse conditions. The data is recorded from the medical chart after post-partum hospital discharge. The period covered is: pregnancy, from randomisation to post-partum hospital discharge.

Key secondary outcome(s)

Outcome indicators are assessed from randomisation until post-partum hospital discharge. The following sources are used: prenatal record from treating MD, data recorded in CRF by study nurse at the three follow-up visits, postpartum and newborn hospital chart of mother and baby. The period covered is: pregnancy, from randomisation to postpartum hospital discharge.

1. Preeclampsia
2. Maternal death
3. Severe preeclampsia
4. Preterm delivery less than 32 and less than 37 weeks gestation (gestational age corrected by early ultrasound scan)
5. Intrauterine growth restriction (less than third centile)
6. Perinatal mortality
7. Spontaneous abortion
8. Premature rupture of membranes
9. Antenatal inpatient days
10. Neonatal mortality indicators

Completion date

30/06/2008

Eligibility

Key inclusion criteria

1. The woman is pregnant between 12^{0/7} and 18^{6/7} completed weeks
2. At least 18 years of age
3. Speaks a language known by the medical staff
4. Plans to deliver in a participating hospital

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Daily Vitamin C intake equal or more than 200 mg
2. Daily Vitamin E intake equal or more than 50 IU
3. Uses warfarin (coumadin)
4. Known major foetal abnormalities, including chromosomal anomalies in the current pregnancy
5. Has one of the following conditions:

- 5.1. Untreated hypo/hyperthyroidism
- 5.2. Renal disease with altered renal function (creatinine more than two times the upper limit of the normal range value)
- 5.3. Any collagen vascular disease (including lupus erythromatosus, scleroderma)
- 5.4. Active or chronic hepatitis
- 5.5. Epilepsy
- 5.6. Cancer
- 5.7. Threatened abortion (the woman had two or more miscarriages)
- 5.8. Illicit drug use or alcohol abuse (more than or equal to two drinks a day during current pregnancy)

Date of first enrolment

15/01/2004

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

Argentina

Belgium

Canada

China

Mexico

Study participating centre

Hôpital Sainte-Justine

Montréal

Canada

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Sponsor information

Organisation

Hospital Sainte-Justine (Montréal) (Canada)

ROR

<https://ror.org/01gv74p78>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-62005)

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		01/03/2010	15/09/2025	Yes	No
Interim results article	interim results	01/06/2005		Yes	No
Other publications	Circulating very long-chain saturated fatty acids in early pregnancy: association with blood pressure and weight gain	10/09/2025	15/09/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes