ISRCTN85024310 https://doi.org/10.1186/ISRCTN85024310

International Trial of Antioxidant for the Prevention of Preeclampsia

Submission date	Recruitment status	[ ] Prospectively registered
26/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/11/2009	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.gereq.net/intapp

Contact information

Type(s)
Scientific

Contact name
Dr William D. Fraser

Contact details
Hôpital Sainte-Justine
Département d'Obstétrique-Gynécologie
3175, Chemin de la Côte-Ste-Catherine
4e Étage, Bloc 9
Local 4986-B
Montréal
Canada
H3T 1C5
+1 514 345 4931 ext. 4155
william.fraser@umontreal.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
15/01/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
10000 low risk; 2500 high risk

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
H3T 1C5

Sponsor information

Organisation
Hospital Sainte-Justine (Montréal) (Canada)

Sponsor details
3175 Chemin Côte Ste-Catherine
Montréal
Canada
H3T 1C5

Sponsor type
Hospital/treatment centre

Website
http://www.chu-sainte-justine.org/Accueil/default.aspx

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

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?
Interim results article	interim results	01/06/2005		Yes	No