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Dark chocolate in pregnancy study

Submission date	Recruitment status	[X] Prospectively registered
12/12/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2012	Pregnancy and Childbirth	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.chocolatestudy.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCT0076-3

Study information

Scientific Title
A randomised controlled trial of dark chocolate in pregnancy for reduction in incidence of pre-eclampsia

Study objectives
That daily dark chocolate (>70% cocoa) from 10 to 32 weeks of gestation reduces the incidence of pre-eclampsia compared to no chocolate

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
Women are recruited in very early pregnancy, and the study group takes 20 grams of 70% dark chocolate daily from 10 to 32 weeks.
Control group just keeps a food diary.
Follow-up continues until 7 days post-partum.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Diagnosis of pre-eclampsia by seven days post-delivery

Secondary outcome measures
1. Gestational diabetes
2. Birthweight percentile

Overall study start date
01/04/2012

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Primigravid women who are enrolled prior to 10 completed weeks of gestation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
800

Key exclusion criteria
1. Pre-existing hypertension
2. Pre-existing diabetes

Date of first enrolment
01/04/2012

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Australia

Study participating centre
John James Medical Centre
Deakin

Australia
2605

Sponsor information

Organisation
James Cook University (Australia)

Sponsor details
c/o Ms Cindy Woods
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Australia
QLD 4870

Sponsor type
University/education

Website
http://www.jcu.edu.au

ROR
https://ror.org/04gsp2c11

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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