Dark chocolate in pregnancy study

| Submission date 12/12/2011 | Recruitment status No longer recruiting | [X] |
|-------------------------------------|---|------|
| Registration date 18/01/2012 | Overall study status Completed | [] S |
| Last Edited 18/01/2012 | Condition category Pregnancy and Childbirth | [] I |

| [X] | Prospectively | registered |
|-----|---------------|------------|
| | | 5 |

- [_] Protocol
-] Statistical analysis plan
-] Results
-] Individual participant data
- [] 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

Contact name Dr Stephen Robson

Contact details

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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 preeclampsia

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

Gestational diabetes
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 P.O. Box 6811 Cairns 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