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A randomised controlled trial of vitamins C and E to prevent pre-eclampsia in type one diabetic pregnancy

Submission date
25/11/2003

Recruitment status
No longer recruiting

Registration date
31/03/2004

Overall study status
Completed

Last Edited
19/06/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Women with type 1 diabetes are up to four times more likely to develop high blood pressure during pregnancy (pre-eclampsia) when compared to a woman without diabetes. A recent study suggested that taking vitamin C and Vitamin E supplements may prevent women from developing pre-eclampsia, but this needs to be confirmed in larger studies. This is a study to find out if taking vitamin E and vitamin C supplements during pregnancy can prevent pre-eclampsia in women who have type 1 diabetes.

Who can participate?
The DAPIT study aims to recruit about 756 women with type 1 diabetes, over 16 years of age, from NHS antenatal-metabolic clinics across Northern Ireland, North West England and Scotland.

What does the study involve?
Women who take part in the study will be given 2 capsules to take each day throughout pregnancy. These may contain vitamin C and vitamin E or may be dummy (placebo) capsules. Neither the woman nor the doctor looking after her will know whether she is receiving vitamins or dummy tablets. Half of the patients in the study will receive vitamins, and the other half will receive placebo. Women will attend antenatal clinic every 2 weeks throughout pregnancy as normal, will be asked to complete a short (15 minutes) questionnaire about their diet after 26 weeks of pregnancy, and an extra blood sample will be taken at the first visit and after 26 and 34 weeks of pregnancy to measure levels of vitamins and biochemical markers which may be linked to pre-eclampsia. After pregnancy, we would like to assess the health of the baby at a routine post-natal visit which will occur approximately 6 weeks after delivery. This assessment will include measurement of height, weight and head circumference and assessment of development as well as a normal clinical examination.

What are the possible benefits and risks of participating?
For women who receive vitamin C and vitamin E during the study, it is possible that their risk of developing pre-eclampsia may be reduced. However, we do not know if this is the case. The information we get from this study may help us to treat pregnant patients with diabetes better.

In particular, it will allow us to decide in the future whether all pregnant women with diabetes should be recommended to take vitamin supplements or whether this is a waste of time. The main disadvantage of taking part in the study is the need to take two capsules once per day. In addition, women will be asked to complete an additional dietary questionnaire as described above and to provide three blood samples during the course of your pregnancy.

Where is the study run from?
Queen's University Belfast and Belfast Health and Social Care Trust.

When is the study starting and how long is it expected to run for?
Recruitment started in 2003 and ended in 2008.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
Professor David McCance
david.mccance@belfasttrust.hscni.net

Study website
http://www.qub.ac.uk/cm/med/DAPITfrontpage.htm

Contact information

Type(s)
Scientific

Contact name
Dr David McCance

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Regional Centre for Endocrinology and Diabetes
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

067028

Study information

Scientific Title
A randomised controlled trial of vitamins C and E to prevent pre-eclampsia in type one diabetic pregnancy

Acronym
DAPIT- the Diabetes And Pre-eclampsia Intervention Trial

Study objectives
Double-blind randomised multicentre placebo-controlled trial of Vitamin C 1000 mg and Vitamin E 400 IU or placebo tablets daily from eight to 22 weeks gestation until delivery to determine whether supplementation with vitamin C and vitamin E from early pregnancy will reduce the risk of developing pre-eclampsia in pregnant women with type one diabetes.

On 11/06/2008 the overall trial end date was changed from 30/09/2007 to 31/01/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Multi-centre Research Ethics Committee, 09/09/2002, ref: MREC/02/7/16

Study design
Double-blind randomised multicentre placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Interventions
Vitamin C 1000 mg and vitamin E 400 IU or placebo daily from recruitment (eight to 22 weeks gestation) until delivery.

Intervention Type

Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin C 1000 mg and Vitamin E 400 IU

Primary outcome measure
Incidence of pre-eclampsia, measured after delivery

Secondary outcome measures
1. Endothelial activation, measured at baseline, 26 weeks gestation and 34 weeks gestation
2. Birthweight centile, measured after delivery

Overall study start date
01/06/2003

Completion date
31/01/2009

Eligibility

Key inclusion criteria
Women with type one diabetes preceding pregnancy presenting before 22 weeks gestation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
756

Key exclusion criteria
1. Warfarin treatment
2. Multiple pregnancy
3. Gestational diabetes
4. Current or previous (within the last six weeks) ingestion of preparations containing vitamin C (more than 500 mg/day) or vitamin E (200 IU/day)

Date of first enrolment
01/06/2003

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Regional Centre for Endocrinology and Diabetes
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
The Royal Group of Hospitals and Dental Hospital Health and Social Services Trust (UK)

Sponsor details
Royal Research Office
First Floor, Education Centre
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.royalhospitals.org/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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?
Protocol article	protocol at:	01/10/2004		Yes	No
Results article	results	24/07/2010		Yes	No
Results article	results	01/01/2015		Yes	No