ISRCTN33885819 https://doi.org/10.1186/ISRCTN33885819

Primary prevention of gestational diabetes among women at risk: a cluster-randomized controlled trial

Submission date
12/09/2007

Recruitment status
No longer recruiting

Registration date
03/10/2007

Overall study status
Completed

Last Edited
06/03/2013

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Riitta Luoto

Contact details
UKK Institute
post box 30
33501
Tampere
Finland
33501
riitta.luoto@uta.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Women at risk (overweight, age 40 years or older, earlier macrosomic child, diabetic first stage relatives) will receive intensified diet and physical activity counselling, which prevents their gestational diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Pirkanmaa Hospital District. Approved on 24/02/2007. Amendments approved on 11/09/2007 (ref: R02630)

Study design
A cluster-randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
14 counties are participating in the trial. They are randomised to the intervention and control groups (7 counties each).

Intervention group: Intensified, tailored diet and physical activity counselling during five scheduled visits to a public health nurse in maternity health care. Visits take place at 8-9, 16-18, 22-24, 32-34 and 36-37 pregnancy weeks. In addition to physical activity counselling, participants have monthly meetings with peers guided by a physiotherapist.

Participants in the maternity health care in control counties receive usual care only.

(See ISRCTN21512277 for pilot study)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Prevention of gestational diabetes, assessed by:
1. Oral glucose tolerance test during pregnancy weeks 26-28
2. Weight of the newborn

Secondary outcome measures
1. Maternal weight development. Maternal weight will be measured 5 times during pregnancy, on pregnancy weeks 8-9, 16-18, 22-24, 32-34 and 36-37, and 6-8 weeks after delivery.
2. Child weight development, followed one year after delivery.
3. Need of insulin treatment during pregnancy. This will be determined at time of possible GDM diagnosis (earliest 26-28th week of pregnancy based on Oral Glucose Tolerance Test [OGTT]).

Overall study start date
15/09/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Pregnant women in their 8-12th pregnancy week and with at least one of the following criteria:
1. Body mass index at least 25 kg/m2
2. Age at least 40 years
3. History of gestational diabetes or macrosomic child
4. Type 1 or 2 diabetes in any of the first stage relatives

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
1. Age < 18 years
2. Type 1 or 2 diabetes before pregnancy

3. Twin pregnancy or otherwise problematic pregnancy based on physician's opinion
4. Physical disability preventing from exercising
5. Substance abuse or history of severe mental illness

Date of first enrolment
15/09/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Finland

Study participating centre
UKK Institute
Tampere
Finland
33501

Sponsor information

Organisation
The Urho Kaleva Kekkonen (UKK) Institute for Health Promotion Research (Finland)

Sponsor details
Post box 30
Tampere
Finland
33501
uktutkimus@uta.fi

Sponsor type
Research organisation

Website
http://www.ukkinstituutti.fi/en/

ROR
https://ror.org/05ydecq02

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (USA)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Ministries of Education and Social Affairs and Health (Finland)

Funder Name
Diabetes Research Fund (Finland)

Funder Name
Pirkanmaa Hospital District (EVO) (Finland)

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?
Results article	results	03/08/2010		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	05/09/2012		Yes	No
Other publications	cost-effectiveness	01/09/2013		Yes	No