

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

Submission date
12/09/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
03/10/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/03/2013

Condition category
Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

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)

Primary study design

Interventional

Study design

A cluster-randomized controlled trial.

Study type(s)

Prevention

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(s)

Prevention of gestational diabetes, assessed by:

1. Oral glucose tolerance test during pregnancy weeks 26-28
2. Weight of the newborn

Key secondary outcome(s)

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]).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/05ydecq02>

Funder(s)

Funder type

Government

Funder Name

National Institutes of Health (USA)

Alternative Name(s)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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