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A comparison of low glycaemic index carbohydrate diet versus no dietary intervention in pregnancy to prevent recurrence of a large baby

Submission date
22/04/2009

Recruitment status
No longer recruiting

Registration date
10/08/2009

Overall study status
Completed

Last Edited
14/01/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] 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

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial of low glycaemic index carbohydrate diet versus no dietary intervention in the prevention of recurrence of foetal macrosomia

Study objectives
Current information as of 01/09/2009:
1. Amongst women at risk of a macrosomic baby, a low glycaemic index diet in pregnancy is associated with reduction in birth weight centiles when compared to no dietary intervention
2. Amongst women at risk of a macrosomic baby, a low glycaemic index diet in pregnancy is associated with less maternal weight gain compared to no dietary intervention

Initial information at time of registration:
1. Amongst women at risk of a macrosomic baby, a low glycaemic index diet in pregnancy is associated with reduction in birth weight centiles when compared to no dietary intervention
2. Amongst women at risk of a macrosomic baby, a low glycaemic index diet in pregnancy is associated with less maternal weight gain compared to no dietary intervention
3. A low glycaemic index diet in pregnancy when compared to no dietary intervention is associated with differences in urinary metabolomics
4. A low glycaemic index diet in pregnancy when compared to no dietary intervention is associated with differences in cord leptin, insulin-like growth factor 1 (IGF-1) and insulin
5. A low glycaemic index diet in pregnancy when compared to no dietary intervention is associated with differences in placental villous and vascular development

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the National Maternity Hospital, June 2006

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Foetal macrosomia

Interventions
Methods:
Women choosing to enter the study will give written informed consent. Data will be collected on those women approached for study participation and who declined to ensure those participating are representative of this entire group.

Patients will be randomised into two arms: a control arm which will receive no dietary intervention during pregnancy and a diet arm which will be commenced on a low glycaemic index diet from 14 weeks gestation to delivery under dietetic supervision. Each patient in the diet arm will receive an individualised diet which will be energy matched as appropriate to a patients' average caloric intake with the aim of reducing glycaemic load and glycaemic excursions. This diet is eucaloric and is not designed to promote weight loss. In the diet arm, the aim for weight gain during pregnancy will be a 8 - 10 kg for a woman of normal weight and 5 - 7 kg in women with weight greater than 100 kg. In the diet arm each patient will have one dietetic session, in groups of 4 - 6 at 12 - 16 weeks gestation, with the aim of commencing the diet at 16 weeks gestation.

At booking visit all patients will have their height and weight recorded and their BMI will be calculated (maternal weight [kg]/height [m^2]). Additional demographic data including smoking history, socio-economic group (SEG) and paternal weight and height will be recorded.

In addition to routine care the following additional tests will be performed:
1. Food frequency questionnaire at 12, 28 weeks gestation and 3 months post-partum. Average weekly exercise will also be recorded as part of this questionnaire. The food questionnaire will use questions from section I of the 'SLAN (Survey of Lifestyle, Attitudes and Nutrition) National Health and Lifestyle Survey' 2002. This has been validated in an Irish population. At 3 months postpartum the questionnaire will assess compliance to the low glycaemic index diet following pregnancy. Information at 12 weeks will allow baseline information to be obtained. Assessment at 28 weeks gestation will assess compliance to the diet in the intervention arm.
2. At each visit maternal weight will be recorded: 12, 20, 28, 34, 36, 38, 40 weeks' gestation
3. At 12 weeks fasting blood glucose [and insulin, leptin and IGF-1 - removed 01/09/2009], mid upper arm circumference and body mass index will be taken. [This will assess baseline insulin resistance and glucose status. Assessment of leptin and IGF-1 will allow comparison between foetal and neonatal size and maternal growth factors - removed 01/09/2009]
[4. Urine analysis for nitrogen and metabolomic profile. This will assess the effect of diet on metabolism as one may expect protein and kreb cycle products to differ between the groups. Urinary nitrogen measurement will be an indicator of protein breakdown for energy substrate - removed 01/09/2009]
5. Glucose challenge test at 28 weeks. It is important to determine the presence of gestational diabetes in this group. If gestational diabetes is present care will continue in the multidisciplinary diabetic clinic.
6. Foetal growth ultrasound at 34 weeks. Foetal biometry including anterior abdominal wall thickness will be measured to ensure normal foetal growth velocity and for comparison to the birth weight.
[7. At the 34 week scan, patients in the diet group will be asked to complete a simple questionnaire comprising 5 questions to determine compliance with diet
8. Cord bloods for insulin, leptin and IGF-1. These will be correlated with maternal growth factors, maternal and foetal weight.
9. Placental biopsy for assessment of placental architecture. A placental sample will be retained in both arms of the study for later analysis to determine if there is a relationship between placental villous and vascular morphology and recurrence of macrosomia - removed 01/09/2009]
10. Neonatal anthropometry. At delivery, infant birth weight, infant length and head circumference will be recorded in all cases as is current routine practice. [The ponderal index will be computed - removed 01/09/2009]

Randomisation:
This will be achieved using computer generated allocations in a ratio of 1:1 contained in sealed opaque envelopes.

Intervention Type
Other

Primary outcome(s)
Mean birth weight centiles and ponderal indices in each group, measured at 14 weeks, 28 weeks, 34 weeks, at birth and 3 months post-partum

Key secondary outcome(s))
Current information as of 01/09/2009:
Differences between the two groups in maternal weight gain in pregnancy, measured at 14 weeks, 28 weeks, 34 weeks, at birth and 3 months post-partum

Initial information at time of registration:
Differences between the two groups:
1. Maternal weight gain in pregnancy
2. Urinary metabolomics
3. Cord insulin, leptin and IGF-1
4. Placental weight, villous and vascular development
Outcomes will be measured at 14 weeks, 28 weeks, 34 weeks, at birth and 3 months post-partum

Completion date
30/12/2009

Eligibility

Key inclusion criteria
Secundigravid women of reproductive age (greater than 18 years and less than 45 years) whose first baby was macrosomic (birth weight greater than 4000 g) will be recruited at first booking visit from the antenatal clinic at the National Maternity Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment

0

Key exclusion criteria
1. Diabetes
2. Other medical disorders
[3. Weight greater than 120 kg - removed 01/09/2009]
4. Poor previous pregnancy outcome

Date of first enrolment
01/01/2007

Date of final enrolment
30/12/2009

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Dublin
Ireland
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Sponsor information

Organisation
Health Research Board (HRB) (Ireland)

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (HRB) (Ireland)

Alternative Name(s)

HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	31/10/2013		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	secondary analysis results	01/11/2014		Yes	No
Results article	results	07/10/2015		Yes	No
Results article	secondary analysis results	02/08/2017		Yes	No
Results article	results	16/10/2017		Yes	No
Results article	results	01/07/2020	13/11/2019	Yes	No
Results article	DASH (Dietary Approaches to Stop Hypertension) dietary pattern and maternal blood pressure in pregnancy	01/10/2020	09/08/2021	Yes	No
Results article	insights from the ROLO young person's advisory group	09/02/2023	13/02/2023	Yes	No
Protocol article	protocol	23/04/2010		Yes	No
Other publications	Infant Feeding questionnaire was sent to all participants attending a 10-year study visit and data used in the ROLO Longitudinal Cohort	08/01/2026	14/01/2026	Yes	No