# 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	<b>Recruitment status</b> No longer recruiting
Registration date 10/08/2009	<b>Overall study status</b> Completed
Last Edited 13/02/2023	<b>Condition category</b> 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

**Contact name** Prof Fionnuala McAuliffe

### **Contact details**

UCD Obstetrics & Gynaecology UCD School of Medicine and Medical Science University College Dublin National Maternity Hospital Holles Street Dublin Ireland 2 +353 (0)1 637 3216/3296 fmcauliffe@nmh.ie

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

#### ClinicalTrials.gov number

Secondary identifying numbers 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:

 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
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
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

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

#### 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.

 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]
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

**Phase** Not Applicable

#### Primary outcome measure

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

#### Secondary outcome measures

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

### Overall study start date

01/01/2007

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

#### **Age group** Adult

**Lower age limit** 18 Years

**Sex** Female

**Target number of participants** 700 women

#### Key exclusion criteria

Diabetes
Other medical disorders
Weight greater than 120 kg - removed 01/09/2009
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 2

## Sponsor information

**Organisation** Health Research Board (HRB) (Ireland)

Sponsor details

73 Lower Baggot St Dublin Ireland 2 +353 (0)1 234 5000 hrb@hrb.ie

**Sponsor type** Government

Website http://www.hrb.ie

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**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

**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?
<u>Protocol</u> article	protocol	23/04 /2010		Yes	No
<u>Results</u> article	results	31/10 /2013		Yes	No
<u>Results</u> article	results	01/08 /2014		Yes	No
<u>Results</u> article	secondary analysis results	01/11 /2014		Yes	No
<u>Results</u> article	results	07/10 /2015		Yes	No
<u>Results</u> article	secondary analysis results	02/08 /2017		Yes	No
<u>Results</u> article	results	16/10 /2017		Yes	No
<u>Results</u> article	results	01/07 /2020	13/11 /2019	Yes	No
<u>Results</u> article	DASH (Dietary Approaches to Stop Hypertension) dietary pattern and maternal blood pressure in pregnancy	01/10 /2020	09/08 /2021	Yes	No
<u>Results</u> article	insights from the ROLO young person's advisory group	09/02 /2023	13/02 /2023	Yes	No