

WEight Loss Looking for Baby And mum's BETter outcomes (WELLBABE)

Submission date 12/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/02/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to see whether a reduced calorie diet can be used to treat diabetes that develops during pregnancy (gestational diabetes). We know that this treatment can be very successful for people with late-onset (type 2) diabetes; the question is whether it can also be used to treat gestational diabetes. We are also interested in the effects of the diet on the body, in particular the effect on the liver. It is thought that gestational diabetes occurs due to too much fat in the liver. This study looks to see whether liver fat is reduced by diet.

Who can participate?

Pregnant women with gestational diabetes. Gestational diabetes is usually diagnosed after 20 weeks gestation by an oral glucose tolerance test arranged by your NHS midwife or antenatal clinic. Women can enter the study between 20 and 32 weeks gestation.

What does the study involve?

The study involves two visits to the Newcastle Magnetic Resonance Centre. At each visit you will be asked not to eat or drink overnight. You will have a magnetic resonance scan of the liver. This is perfectly safe in pregnancy. You will then be given breakfast (cereal, bread roll, margarine, jam and fruit juice). Blood samples will be taken over the next three hours to measure your body's response to breakfast. During your first visit you will be seen by a dietician. We will explain how to reduce your calorie intake to 1,200 kcal. Food suggestions, recipes and portion sizes will be discussed in order to give you a balanced diet containing all necessary nutrients. You will be asked to keep a food diary on MyFitnessPal (a smartphone app). We will show you how to do this. The diary is reviewed regularly by one of the research team and we will contact you by text or telephone regularly during the diet. After 4 weeks of dieting you will be asked to return to the Newcastle Magnetic Resonance Centre for a repeat scan of the liver and meal test. We will be able to tell you how much fat you have lost from the liver and see the effect of the diet on your glucose control during the meal.

What are the possible benefits and risks of participating?

The main benefit of the study is an improvement in your glucose control. This is of huge benefit to both you and your baby and reduces the risks associated with gestational diabetes. Additionally, there are benefits of a more healthy weight in terms of reducing pregnancy risks

such as blood clots and infection. You will benefit from more intense medical input during your pregnancy. You will gain knowledge about your body during pregnancy and get feedback with regards to the effect of diet on your metabolism. There are no risks of participating in this study.

Where is the study run from?

The study recruits patients from the Obstetric Medicine Antenatal Clinic at the Royal Victoria Infirmary, Newcastle upon Tyne Hospitals Foundation NHS Trust. The study is run at the Newcastle Magnetic Resonance Centre, Newcastle University (UK).

When is the study starting and how long is it expected to run for?

The study starts in January 2015 and is expected to run until August 2015.

Who is funding the study?

The study is funded by a grant from the North East Diabetes Trust (UK).

Who is the main contact?

Dr Ken Hodson

kenneth.hodson@ncl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Kenneth Hodson

ORCID ID

<http://orcid.org/0000-0003-3091-6952>

Contact details

Newcastle Magnetic Resonance Centre

Campus for Ageing and Vitality

Newcastle University

Newcastle upon Tyne

United Kingdom

NE4 5PL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Dietary intervention for the treatment of gestational diabetes: a magnetic resonance study

Acronym

WELLBABE

Study objectives

Calorie restriction in women with gestational diabetes reduces liver fat, thereby improving insulin resistance and improved glycaemic control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East - Newcastle & North Tyneside 2, 22/10/2014, ref: 14/NE/1085

Study design

Interventional non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Gestational diabetes: hyperglycaemia that is first recognised in pregnancy

Interventions

Dietary intervention: calorie reduction to 1,200 kcal for four weeks.

Magnetic resonance spectroscopy will be used to quantify liver fat before and after a four-week dietary intervention. A standardised meal test will be used to quantify insulin resistance and glycaemic control.

Intervention Type

Behavioural

Primary outcome measure

1. Liver fat – measured at baseline and after 4 weeks of dietary intervention by magnetic resonance spectroscopy
2. Glycaemic control – measured by home blood glucose monitoring in the first and fourth weeks

Secondary outcome measures

1. Insulin/C peptide/glucose response to a standardised meal test. Measured at baseline and after 4 weeks of dietary intervention
2. Lipid profile – measured using nuclear magnetic spectroscopy at baseline and 4 weeks of dietary intervention
3. HBA1c – measured at baseline and after 4 weeks of dietary intervention
4. Feasibility and acceptability of dietary intervention in pregnancy (qualitative study) – assessed by semi-structured interview after the dietary intervention and analysed using the theory domain framework

Overall study start date

01/01/2015

Completion date

01/01/2017

Eligibility

Key inclusion criteria

1. Female
2. Greater than 20 weeks pregnant
3. Gestational diabetes (oral glucose tolerance test greater than/equal to 5.1 mmol/l, or 2-hour glucose greater than/equal to 7.8 mmol/l)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

16

Key exclusion criteria

Contraindication to MRI:

1. Pacemaker/ferromagnetic implants
2. Metallic fragments in eye
3. Piercings that cannot be removed
4. Claustrophobia

Date of first enrolment

05/01/2015

Date of final enrolment

01/08/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Newcastle upon Tyne Hospitals NHS Foundation Trust**

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Study participating centre**Newcastle Magnetic Resonance Centre**

Newcastle University Campus for Ageing and Vitality

Newcastle upon Tyne

United Kingdom

NE4 5PL

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

England

United Kingdom

NE1 4LP

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

North East Diabetes Trust (UK)

Results and Publications

Publication and dissemination plan

The results from this study will be written up for publication as a scientific paper in an established medical journal. Expected completion and publication will be by August 2016.

Intention to publish date

01/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No