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

**Submission date**
12/02/2015

**Recruitment status**
No longer recruiting

**Registration date**
24/02/2015

**Overall study status**
Completed

**Last Edited**
23/02/2015

**Condition category**
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 acceptibility 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 |