We would like you to consider participating in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
The purpose of this study is to find out whether genetic variation in the amount of insulin we release into blood could influence fat metabolism.

Why have I been invited?
You are registered with the "Cambridge BioResource" and had therefore declared your interest in taking part in research studies. In total we hope to involve 52 male adults.

Who is organising the study?
The Cambridge BioResource and the Department of Paediatrics based at Addenbrooke's Hospital in Cambridge.

What will happen if I take part?
If you agree to take part, we will ask you to come to the Clinical Research Facility at Addenbrooke's Hospital on 2 occasions. You need to avoid rigorous exercise and alcohol 48 hours before each visit.

The first time you visit, we ask you to attend in the morning before having breakfast. We then measure your blood sugar level with a fingerprick blood test. You then drink a sugary drink and the fingerprick blood test is repeated after 1 and 2 hours. We then give you a normal meal so that you can go home.

This "Oral Glucose Tolerance Test" (OGTT) assesses how well you handle sugar. If the test is normal, we will ask you to attend for the following second visit:

You join us at the research facility at around 7pm. Your height, weight and waist circumference are recorded. You are then given the final meal of the day and we place a small plastic tube (known as cannula or drip) into a vein of one arm, which can cause mild discomfort. The cannula is used for taking blood samples for various hormone levels overnight and we will do our best not to wake you.

The following morning you undergo a short procedure known as "calorimetry", which looks at how fast you use your body fat and sugar. For this we place a transparent canopy over your head and analyse the air you breathe in and out.

We then measure the amount of fat in your belly, leg muscle and liver using a magnetic resonance imaging (MRI) scan, which takes about 1 hour. You may listen to your own music if you wish. The scan uses magnetic fields and radio signals, so it does not involve X-rays. You should not have the scan if you have metal implants in your body (for example following surgery).

Following the MRI, we ask you to drink a milkshake so we can measure how much insulin you release into your bloodstream. During this time we also ask you to provide a urine sample.

Finally, we undertake a "DXA" scan to measure your whole body's amount of fat. The scan involves you lying still on a bed whilst the scanner bar passes over you. It takes a few minutes and works much like an X-ray. The X-ray exposure is very small and equivalent to roughly 1 hour from natural sources of background radiation in the environment.

Possible risks/side effects
The total amount of blood taken during the whole study is about 230 ml, which is half of a blood donation.

The MRI scan will be reviewed by a radiologist. There is a chance of less than 1 in 100 that your MRI scan shows an abnormality of which you are unaware. If this is the case, you will be advised of this and counselled by one of the study doctors. In a very small number of cases, such a finding may have implications for future employment and insurance.

Possible benefits
Participation in this study will not benefit you as an individual but will help us understand the disease diabetes.

Who has reviewed and is funding the study?
This study has been reviewed and given a favourable opinion by the East of England-Norfolk Research Ethics Committee (reference 12/EE/0396). The study is jointly funded by the Cambridge University Department of Paediatrics and the research commission of the Heinrich Heine University, Düsseldorf, Germany.

What if there is a problem?
Complaints: if you have a concern about any aspect of the study, please ask the research team. If you wish to complain formally, you can contact the Patient Advice and Liaison Service (PALS), 01223-216756 or pals@addenbrookes.nhs.uk.
Harm: Although unlikely, if you are harmed due to someone's negligence, you may have grounds to legal action but you may have to pay your legal costs.

Who will have access to the data?
Strict confidentiality will be maintained at all times. Only initials and a number will identify study participants. Names and addresses will not be used. The study files are kept in a locked room at the University Department of Paediatrics. The research team will have access to your data, which may also be looked at by regulatory authorities for audit or monitoring purposes.

Will my GP be informed?
With your permission we would inform your GP that you are taking part in a research study. In the unlikely event of encountering a worrying result, we will ask you if it is ok to inform your GP.

What will happen to the study results?
Once the study is finished, the data will be entered into a computer programme for mathematical testing. Participants will be given a summary whole study's findings. The study results may be presented at scientific meetings and published in a scientific journal.

Will I be reimbursed?
We are able to cover travelling expenses and offer £150 for your time and inconvenience.

Withdrawal clause
If you decide to participate in this study, please remember that you are free to withdraw at any time without explanation. If you withdraw, this will not affect your future management in any way.

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UNIVERSITY OF CAMBRIDGE

Cambridge University Hospitals NHS
NHS Foundation Trust

Department of Paediatrics

"The relationship between pancreatic β-cell function and lipid turnover"

Information sheet

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