

Effects of lowering blood glucose on T cell activation in fat tissue

Submission date 20/12/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/01/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15534

Study information

Scientific Title

Effects of lowering blood glucose on T Lymphocyte activation in human adipose tissue

Study objectives

Overweight and obesity are major problems and their complications such as cardiovascular disease and type 2 diabetes mellitus (T2DM) pose great burdens on our healthcare systems. There is accumulating evidence to support obesity being a chronic inflammatory disorder mediated in part by expansion of adipose (fat) tissue (AT).

In addition to adipocytes (fat cells), AT contains a range of other cell types including some immune (white blood) cells. Relative proportions of immune cell subpopulations and interactions between different cell types within AT may be important in the development of T2DM.

We want to investigate some of the potential mechanisms leading to adipose tissue dysfunction and how the various cell types in adipose tissue contribute. In particular we are interested in the role of T lymphocytes since these cells are found in adipose tissue, but are normally involved in responses to infections. Our previous research has suggested that there may be important differences in the activation status of certain immune cells located in AT with increased overweight and further relationships with glucose and insulin sensitivity. Since insulin resistance and sensitivity can be rapid to respond to dieting and exercise, we would like to investigate whether immune cells present in subcutaneous adipose tissue may have a role in these early improvements in metabolic health.

Our subjects will include metabolically healthy and unhealthy overweight individuals aged between 45-65 years who fit our criteria for inclusion. After taking some preliminary measurements and monitoring of normal daily activities, subjects will modify normal diet and activity for 10 days to reduce postprandial glucose and will attend 1 session of Laboratory testing before and 1 after this period which will take place in the Physiology Laboratories at the University of Bath.

In this study we hope to learn more about the development of diseases associated with being overweight/obese.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/SW/0267

Study design

Non-randomised interventional and observational; Design type: Prevention, Cohort study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Diet and activity modification, For 10 days, participants will be instructed to consume a glucose lowering diet. This will involve modifications to their normal diet such as replacing high GI foods with lower GI foods.

Participants will also be asked to incorporate some regular activity breaks throughout the 10 days. This involves participants going for a light 2 minute walk every 30 minutes to reduce sedentary time over a period of 8h per day for a total of 30 minutes extra activity per day.

Study Entry : Registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

T cell number and activation in adipose tissue; Timepoint(s): Pre and post intervention

Secondary outcome measures

1. Adipose tissue cytokine secretion; Timepoint(s): Pre and post intervention
2. Adipose tissue gene expression; Timepoint(s): Pre and post intervention
3. Macrophage number and activation in adipose tissue; Timepoint(s): Pre and post intervention
4. T Lymphocyte and monocyte numbers and activation in blood; Timepoint(s): Pre and post intervention

Overall study start date

06/01/2014

Completion date

01/08/2014

Eligibility**Key inclusion criteria**

1. Male or postmenopausal* female
2. Aged between 45 to 65years
3. Waist circumference >94cm (males) or >80cm (females)
4. Weight stable for more than 3 months (no change in weight +/- 3%)

Non-smoker

Group 1 participants will be overweight with 'normal glucose tolerance' as defined by 2h oral glucose tolerance test (blood glucose <7.8 mmol/L at 2h post 75g glucose drink)

Group 2 participants will be overweight with 'impaired glucose tolerance' (blood glucose >7.8 mmol/L but <11.1mmol/L at 2h post 75g glucose drink)

*postmenopausal defined as no menstruation for at least 1 year (Witteman, Grobbee et al. 1989).; Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 45 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 22; UK Sample Size: 22; Description: 11 overweight/obese with normal glucose tolerance 11 overweight/obese with impaired glucose tolerance

Key exclusion criteria

1. Personal history of/existing diabetes, cardiovascular disease, metabolic disease or dyslipidaemia
2. Taking medications that may influence lipid or carbohydrate metabolism or immune system function
3. Perform >150minutes/week moderate intensity exercise

Date of first enrolment

06/01/2014

Date of final enrolment

01/08/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department for Health

Bath

United Kingdom

BA2 7AY

Sponsor information

Organisation

University of Bath (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/002h8g185>

Funder(s)

Funder type

Industry

Funder Name

BBSRC Industrial CASE Partnership Studentship with Unilever (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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

