

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

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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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 (Witteaman, Grobbee et al. 1989).; Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 45 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Department for Health

Bath

United Kingdom

BA2 7AY

**Sponsor information****Organisation**

University of Bath (UK)

**ROR**

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

**Funder(s)**

Funder type

Industry

### Funder Name

BBSRC Industrial CASE Partnership Studentship with Unilever (UK)

## Results and Publications

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No