ISRCTN87451268 https://doi.org/10.1186/ISRCTN87451268

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

Submission date	Recruitment status	[X] Prospectively registered
20/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/01/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Rebecca Travers

Contact details
Department for Health
Eastwood 22/23
The Avenue
Claverton Down
Bath
United Kingdom
BA2 7AY
+44 1225 386319
R.L.Travers@bath.ac.uk

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 (Witteman, 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?
HRA research summary			28/06/2023	No	No