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The role of resistant starch in the treatment of insulin resistance

Submission date	Recruitment status	[_] Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2012	Nutritional, Metabolic, Endocrine	

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
6301

Study information

Scientific Title

Acronym
Resistant Starch

Study objectives

A randomised cross-over dietary intervention study looking at the role of an insoluble dietary fibre in the prevention of type 2 diabetes in participants with metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on the 2nd August 2006 (ref: 06/Q1803/57)

Study design
Single centre randomised interventional prevention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Metabolic and Endocrine; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes)

Interventions
Participants are supplemented with either 40 g/day resistant starch (fibre) for 8 weeks compared to a placebo supplement which is energy matched.

Study entry: single randomisation only

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Resistant starch

Primary outcome(s)
Insulin sensitivity measured with hyperinsulinaemic euglycaemic clamp at end of each 8 week intervention.

Key secondary outcome(s))
1. mRNA expression in adipose tissue biopsies taken at end of each 8 week intervention
2. Postprandial meal handling and arteriovenous uptake of glucose measured at end of each 8 week intervention

Completion date
01/11/2009

Eligibility

Key inclusion criteria
1. Non-diabetic
2. No history of cardiovascular, endocrine or gastrointestinal disease
3. Male and female over the age of 18 years
4. Fasting plasma insulin greater than 60 pmol/l

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2006

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
University of Surrey (UK)

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Results article	results	01/09/2012		Yes	No