ISRCTN56997186 https://doi.org/10.1186/ISRCTN56997186

The role of resistant starch in the treatment of insulin resistance

Submission date	Recruitment status
19/05/2010	No longer recruiting
Registration date	**Overall study status**
19/05/2010	Completed
Last Edited	**Condition category**
06/11/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof David Russell-Jones

Contact details
Egerton Road
Guildford
United Kingdom
GU2 7XX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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 measure
Insulin sensitivity measured with hyperinsulinaemic euglycaemic clamp at end of each 8 week intervention.

Secondary outcome measures
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

Overall study start date
01/11/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 15

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

England

United Kingdom

Study participating centre
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Faculty of Health and Medical Science
Guildford
England
United Kingdom
GU2 7XH

Sponsor type
University/education

Website
http://www2.surrey.ac.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

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?
Results article	results	01/09/2012		Yes	No