

The role of resistant starch in the treatment of insulin resistance

Submission date

19/05/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

19/05/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

06/11/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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)

Primary study design

Interventional

Study design

Single centre randomised interventional prevention trial

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)

The British Diabetic Association, 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