ISRCTN10727538 https://doi.org/10.1186/ISRCTN10727538

Resistant Starch as a complementary treatment for type 2 diabetes

Submission date	Recruitment status
18/11/2011	No longer recruiting
Registration date	**Overall study status**
18/11/2011	Completed
Last Edited	**Condition category**
21/04/2015	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8870

Study information

Scientific Title
Resistant Starch as a complementary treatment for type 2 diabetes

Acronym
DRN 505 (Resistant Starch treatment for T2DM)

Study objectives
Dietary fibres in the diet, such as resistant starch, are known to have many health benefits especially regarding large-bowel health. Resistant starch is of particular interest as it can be easily incorporated into everyday foods without affecting the appearance, taste or texture of that food. Fibres are fermented in the large-bowel by the resident bacteria releasing metabolites known as short-chain fatty acids. These short-chain fatty acids are absorbed into the general circulation and are believed to underlie the other health benefits of dietary fibre, namely increasing the bodies' responsiveness to the hormone insulin and so reducing the risk of developing conditions such as high blood-pressure, type 2 diabetes and heart disease.

Initial studies in our group have shown that resistant starch has beneficial effects on the insulin response in healthy subjects and those at risk of developing diabetes. Due to these findings the current study has been designed to look at the effects of resistant starch in subjects who have well controlled type 2 diabetes and investigate whether there is an improvement in glycaemic control when resistant starch is consumed in addition to an individual's normal diet and treatment.

Participants will be asked to consume the resistant starch or an energy and carbohydrate matched placebo everyday for 12 weeks. At the end of each 12 week period the participants will be asked to attend for 3 study visits where the effects on glycaemic control, insulin sensitivity and body fat storage (by MRI scanning) will be assessed.

The overall aim of the study is to conduct a placebo-controlled crossover dietary intervention study using 40 g/day RS for 12 weeks in patients diagnosed with type 2 diabetes mellitus (T2DM). The following measurements will be taken and compared between the interventions:
1. Isulin sensitivity
2. Changes to glycaemic control
3. HbA1c, fasting insulin sensitivity by homeostatic model assessment (HOMA), plasma lipids

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=8870

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H1101/29

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2, Not Assigned; Disease: Diabetic Control, Metabolic, Nutrition

Interventions
Dietary Intervention, 40g/day resistant starch for weeks compared to matched placebo; Study Entry : Single Randomisation only

Intervention Type
Supplement

Primary outcome measure
11. Glycaemic control
1.1. Hyperinsulinaemic clamp with stable isotopes
2. HbAc
3. Fasting glucose and insulin
Measured at end of intervention

Secondary outcome measures
1. Ectopic fat distribution
1.1. Whole body magnetic resonance imaging (MRI)
2. Vascular function
2.1. Blood pressure and pulse wave analysis
Measured at end of intervention

Overall study start date
01/06/2010

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Males and Females, aged 20 - 65 years
2. Those with T2DM, that has been diagnosed for > 2 years, and

3. Are either diet / exercise controlled or on metformin treatment (or both), which has not been modified in 6 months.
Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 20 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Those who control their diabetes by insulin or sulphonylureas
2. Those with an HbA1c >= 8.5 indicative of poor control
3. Those with certain medical conditions (for example heart disease, gastrointestinal disease, liver disease, type 1 diabetes or endocrine diseases)
4. Those know to suffer from claustrophobia or have metal implants as this would prevent Magnetic resonance spectroscopy (MRS) scanning

Date of first enrolment
01/06/2010

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
London
United Kingdom
GU2 7WG

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
European Institute of Health and Medical Sciences
Edward Duke Of Kent Building
Guildford
England
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Sponsor type
University/education

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	15/04/2014		Yes	No