

# Resistant Starch as a complementary treatment for type 2 diabetes

**Submission date**  
18/11/2011

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
18/11/2011

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
21/04/2015

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ 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. Insulin 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  $\geq 8.5$  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 known 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  
United Kingdom  
GU2 7TE

**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?
<a href="#">Results article</a>	results	15/04/2014		Yes	No