Diabetes Health, Residence and Metabolism in Asians: The DHRMA Study

Submission date Recruitment status Prospectively registered 21/05/2010 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 21/05/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 26/10/2018 Nutritional, Metabolic, Endocrine

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 6811

Study information

Scientific Title

Diabetes Health, Residence and Metabolism in Asians: The DHRMA Study

Acronym

DRN 335 DHRMA

Study objectives

The DHRMA study will focus on testing two distinct hypotheses using two separate studies:

- 1. Glycaemic index study:
- 1.1. The glycaemic index (GI) of DHRMA basmati rice (KETT less than 35%) is lower than UK traditional basmati rice or UK Super Basmati (KETT greater than 40%) and comparable to unrefined rice from rural Gujarat (jya and mysuri kernels); and
- 1.2. The GI of DHRMA stone-ground flour is lower than UK white and brown and wholemeal chapatti flour, but comparable to hand-milled flour from rural India
- 2. Interventional study:

We will test the hypothesis that intervention with a low GI, carbohydrate rich/low fat diet will result in favourable changes in metabolic, diabetes and CHD risk indices compared to a high GI, carbohydrate rich/low fat diet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 08/H1204/130)

Study design

Single centre randomised interventional prevention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network; Subtopic: Other; Disease: Diabetic Control, Metabolic

Interventions

The use of stone ground flour or rice with a low glycaemic index as compared to the use of flour or rice with a higher glycaemic index.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To determine whether the rice and chappati flour test foods (DHRMA) exhibit a more favourable outcome

Secondary outcome measures

- 1. To develop foods for DHRMA that mimic those available in rural Gujarat
- 2. Diabetes and macrovascular risk
- 3. Glycaemic index (GI)

Overall study start date

31/03/2009

Completion date

30/09/2010

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Planned sample size: 100; UK sample size: 100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

31/03/2009

Date of final enrolment

30/09/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Lyndon

West Bromwich United Kingdom B71 4HJ

Sponsor information

Organisation

Sandwell and West Birmingham Hospitals NHS Trust (UK)

Sponsor details

Lyndon West Bromwich England United Kingdom B71 4HJ

Sponsor type

Hospital/treatment centre

Website

http://www.swbh.nhs.uk/

ROR

https://ror.org/05mzf3276

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (BHF) (UK)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

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?
<u>Protocol</u> <u>article</u>	protocol	02/12 /2011		Yes	No
Abstract results	results presented at European Atherosclerosis Society (EAS) Congress	01/07 /2015		No	No