ISRCTN02839188 https://doi.org/10.1186/ISRCTN02839188

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

Submission date	Recruitment status
21/05/2010	No longer recruiting
Registration date	**Overall study status**
21/05/2010	Completed
Last Edited	**Condition category**
26/10/2018	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] 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

Protocol serial number
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)

Primary study design
Interventional

Study design
Single centre randomised interventional prevention trial

Study type(s)
Prevention

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

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

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Lyndon
West Bromwich
United Kingdom
B71 4HJ

Sponsor information

Organisation

Sandwell and West Birmingham Hospitals NHS Trust (UK)

ROR
https://ror.org/05mzf3276

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

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