

United Kingdom Asian Diabetes Study

Submission date 23/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
2

Study information

Scientific Title

Acronym

UKADS

Study objectives

Structured care for diabetes, tailored to the needs of the Asian community, will improve surrogate endpoints for diabetic complications (and by extrapolation morbidity and mortality) in South Asian patients with type 2 diabetes. This will require the extra resources of Asian link workers, additional practice nurse time and community Diabetes Specialist Nurse input, working to protocols with clearly defined targets.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

A complex intervention package comprising specialist diabetes nurse co-ordinators working with practice nurses to implement protocols for the treatment of blood pressure, blood lipid and blood glucose levels. The protocols use simple treatment algorithms and have strict targets. Practice nurse time and training are protected and enhanced, and practice nurses work with Asian link workers to facilitate cultural acceptability of treatment and compliance. DNA samples will be prepared in order to investigate the genetic determinants of high density lipoprotein (HDL) cholesterol levels and latent autoimmune diabetes of adults (LADA), the genetic susceptibility to microalbuminuria and candidate susceptibility genes for type 2 diabetes and

components of the metabolic syndrome.

Control: usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Achievement of targets as set out in treatment algorithms:

1. Blood pressure (130/80 mmHg)
2. Lipid profile (total cholesterol less than 4.0 mmol/l, low density lipoprotein [LDL] cholesterol less than 2.5 mmol/l, triglycerides less than 2.0 mmol/l)
3. Glycaemic control (HbA1c less than 7.0%)

Secondary outcome measures

1. Development and progression of microalbuminuria and proteinuria
2. Mortality from any cause
3. Micro- and macro-vascular complications

Overall study start date

01/03/2004

Completion date

01/03/2007

Eligibility

Key inclusion criteria

Patients of South Asian ethnic background with type 2 diabetes.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1800

Key exclusion criteria

1. Patients not of South Asian ethnic background
2. Diabetes other than type 2 diabetes

Date of first enrolment

01/03/2004

Date of final enrolment

01/03/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Undergraduate Centre**

Birmingham

United Kingdom

B9 5SS

Sponsor information**Organisation**

Heart of England NHS Foundation Trust (UK)

Sponsor details

Birmingham Heartlands Hospital

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Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Industry

Funder Name

Pfizer Ltd (UK)

Funder Name

Sanofi-Aventis (UK)

Funder Name

Servier Laboratories Ltd (UK)

Funder Name

Merck, Sharp and Dohme - Schering Plough Limited (UK)

Funder Name

Takeda Ltd (UK)

Funder Name

Merck Pharmaceuticals (UK)

Funder Name

Eli Lilly and Company Limited (UK)

Funder Name

Novo Nordisk Ltd (UK)

Funder Name

Boehringer Ingelheim GmbH (Germany)

Funder Name

British Heart Foundation (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?
Results article	results	01/12/2004		Yes	No
Results article	results	24/05/2008		Yes	No
Results article	results	02/09/2009		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/11/2011		Yes	No