

# United Kingdom Asian Diabetes Study

<b>Submission date</b> 23/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/11/2013	<b>Condition category</b> 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

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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%)

**Key secondary outcome(s)**

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

**Completion date**

01/03/2007

**Eligibility****Key inclusion criteria**

Patients of South Asian ethnic background with type 2 diabetes.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Undergraduate Centre**

Birmingham

United Kingdom

B9 5SS

# Sponsor information

## Organisation

Heart of England NHS Foundation Trust (UK)

## 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 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?
<a href="#">Results article</a>	results	01/12/2004		Yes	No
<a href="#">Results article</a>	results	24/05/2008		Yes	No
<a href="#">Results article</a>	results	02/09/2009		Yes	No
<a href="#">Results article</a>	results	01/08/2010		Yes	No
<a href="#">Results article</a>	results	01/11/2011		Yes	No