ISRCTN17526370 https://doi.org/10.1186/ISRCTN17526370

# DRN 725: Chronic Disease Resource Centre Diabetes Division

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 19/11/2012 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 27/03/2013 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 27/03/2013 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
The study aims to recruit individuals with diabetes or a pre-diabetic condition. We will collect information and blood samples from patients once a year at a time convenient to the individual and the research team (normally at the same time as their annual diabetes check). The information collected from this study will be used in research into how diabetes affects individuals in the setting of it being a chronic disease. The aim of this study is to establish a database of information of adult participants diagnosed with impaired glucose tolerance. This database will be used to explore the psycho-social aspects of diabetes in the context of it being a chronic disease. Also, the database will be used to develop partnerships with other researchers to advance diabetes research for the benefit of individuals with diabetes.

Who can participate?
Individuals who are 18 years or older with confirmed diabetes or abnormal glucose tolerance. Individuals must be willing and able to attend annual appointments at clinical study recruitment site centre.

What does the study involve?
The study involves an annual study visit where non-invasive clinical measurements will be taken, along with a questionnaire, blood and urine samples.

What are the possible benefits and risks of participating?
As this study is does not involve any intervention then the risks to participants are minimal.

Where is the study run from?
The study is currently run from the Queen Elizabeth Hospital Birmingham, UK. There is a network of other centres throughout the West Midlands who are also participating in this study.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and is expected to run until April 2022.

Who is funding the study?
Novo Nordisk A/S (USA)

Who is the main contact?
Jayne Robbie
Diabetes Research Unit
Nuffield House
Queen Elizabeth Hospital
Birmingham B15 2TH
UK

# Contact information

### Type(s)
Scientific

### Contact name
Dr Parth Narendran

### Contact details
University of Birmingham
Institute of Biomedical Research
Division of Immunity and Infection
Medical School
Edgbaston
Birmingham
United Kingdom
B15 2TT
p.narendran@bham.ac.uk

# Additional identifiers

### Protocol serial number
12984

# Study information

### Scientific Title
Chronic Disease Resource Centre: What is the natural history of diabetes and its complications?

### Study objectives
The aim of this study is to establish a prospective, observational multi-ethnic cohort of adult participants diagnosed with impaired glucose tolerance. The cohort will encourage academic collaboration for patient benefit and will be characterised by anthropometry, questionnaires, biological samples and co-morbidities forming a resource for epidemiological, clinical and health service research.

The study will aim to recruit all eligible participants from across the West Midlands Birmingham area. A 10 year study will be undertaken to recruit and follow-up 1000 participants, concentrating initially on University Hospitals Birmingham NHS Foundation Trust (UHBFT), before but could be opening to other NHS clinical centres trusts interested in collaborating.

In addition to providing information about the natural history and progression of diabetes, development of complications and co-morbidities it will provide unique information for use in the detection of biomarkers to help predict the progression of complications and to monitor the effectiveness of interventions.

Also, the study will try to accurately categorise patients with potentially different types of diabetes in order to determine whether any factors significantly affect their long-term morbidity or mortality.

In summary the overarching aims and objectives of this study is:
1. To understand the natural history of diabetes in our local population. To determine the incidence of other chronic medical conditions in patients with diabetes.
2. Provide a repository of information for future analysis to help determine potential biomarkers of chronic diseases related to diabetes.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12984

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee West Midlands - Staffordshire, 8th May 2012, ref: 12/WM/0089

## Study design
Non-randomised observational cohort study

## Primary study design
Observational

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Diabetes Research Network

## Interventions
The study is observing changes in participants with diabetes in several domains: depression, quality of life, eating behaviour, risk of sleep apnoea, activities of daily living, employment and productivity, as well as developing a repository of biological samples. The tests will include routine clinical assessment, bone, liver, renal, thyroid blood tests, and questionnaires. Patients will also be invited to undertake more significant testing including analysis of saliva samples, AGE reader, pancreatic stimulation tests.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Micro and macro vascular complications measured at 10 years

### Key secondary outcome(s))
Qualitative and questionnaire based assessment of diabetes related endpoints measured at 10 years

### Completion date
01/04/2022

## Eligibility

### Key inclusion criteria
1. Male or female, age >= 18 years
2. Confirmed diagnosis of diabetes or prediabetes
3. Individuals freely able to attend appointments at the Chronic Disease Research Centre
4. Individuals who are able to undergo the appropriate investigations

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Individuals unable to attend for research visits
2. Individuals who in the clinicians opinion is not appropriate for recruitment into this study

### Date of first enrolment
06/09/2012

### Date of final enrolment
01/04/2022

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre

**University of Birmingham**
Birmingham
United Kingdom
B15 2TT

# Sponsor information

**Organisation**
University of Birmingham (UK)

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Industry

**Funder Name**
Novo Nordisk A/S (UK)

# 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |