

# Diabetes UK Study

<b>Submission date</b> 21/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/09/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Mary Bilous

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

4136

## Study information

**Scientific Title**

Diabetes UK Study

**Acronym**

DRN112 Nurse Led Multifactorial Intervention Study

**Study objectives**

Chronic kidney disease is an independent risk factor for cardiovascular morbidity and mortality. We have previously shown that mortality rates increase exponentially as eGFR declines. This study set out to see whether a multi-factorial cardiovascular risk factor intervention performed by specialist nurses conferred benefit in terms of cardiovascular morbidity and mortality in patients with type 2 diabetes and an estimated glomerular filtration rate (eGFR) less than 90 ml /min/1.73 m<sup>2</sup>.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=4136>

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

MREC, 14/05/2007, ref: 07/Q1001/32

**Study design**

Single-centre randomised interventional treatment trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Nephropathy, Cardiovascular disease, Hypertension, Dyslipidaemia, Diabetic Control, Multiple complications

**Interventions**

1. Achieve blood pressure target less than 130/85 mmHg
2. Achieve HbA1c less than 7%
3. Achieve low density lipoprotein (LDL) cholesterol less than 2 mmol
4. Achieve weight loss of greater than 10% or ideal body weight
5. Detect and correct anaemia to 11 g/dl
6. Correct secondary hyperparathyroidism where detected

7. Increase activity/exercise

8. Stop smoking

Follow up length: 60 months

Study entry: single randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Cardiovascular mortality (obtained from tagging death certificates at OPCS)

### **Secondary outcome measures**

Morbidity (based on patient questionnaire and interrogation of medical records)

### **Overall study start date**

03/12/2007

### **Completion date**

10/12/2012

## **Eligibility**

### **Key inclusion criteria**

1. Type 2 diabetes
2. Estimated glomerular filtration rate (eGFR) 30 - 90 ml
3. Aged 18 - 76 years, either sex

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned sample size: 600; UK sample size: 600

### **Key exclusion criteria**

1. Type 1 diabetes
2. Pregnancy

**Date of first enrolment**

03/12/2007

**Date of final enrolment**

10/12/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

James Cook University Hospital

Middlesbrough

United Kingdom

TS4 3BW

## **Sponsor information**

**Organisation**

South Tees Hospitals NHS Foundation Trust (UK)

**Sponsor details**

James Cook University Hospital

Clinical Trials Unit

Marton Road

Middlesbrough

England

United Kingdom

TS4 3BW

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.southtees.nhs.uk/live>

**ROR**

<https://ror.org/02js17r36>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Diabetes UK (UK)

**Alternative Name(s)**

DIABETES UK LIMITED, British Diabetic Association

**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