

# 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

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## Additional identifiers

**Protocol serial number**  
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

## Study type(s)

Treatment

## 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(s)

Cardiovascular mortality (obtained from tagging death certificates at OPCS)

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**James Cook University Hospital**  
Middlesbrough  
United Kingdom  
TS4 3BW

## Sponsor information

### Organisation

South Tees Hospitals NHS Foundation Trust (UK)

### ROR

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

## Funder(s)

### Funder type

Charity

### Funder Name

Diabetes UK (UK)

### Alternative Name(s)

The British Diabetic Association, 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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration