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# Diabetes UK Study

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 21/10/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 21/10/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 06/09/2019 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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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 m2.

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