

Diabetes UK Study

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/09/2019	Condition category 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 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

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)

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