

Blood pressure control in diabetes in primary care

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

09/12/2008

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Nigel Sturrock

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBG 00XX77

Study information

Scientific Title

Study objectives

To assess the effectiveness of a simple treatment algorithm in primary care in attaining the recommended blood pressure in patients with type 2 diabetes compared to usual practice. To assess the cost-effectiveness of the algorithm for improving blood pressure control in these patients.

Assuming 40% of diabetics have a blood pressure of $<140/80$ an intracluster correlation coefficient (ICC) of 0.02 and an average cluster size of 45 type 2 diabetics per practice. Based on 80% power and 5% two-sided significance level 388 participants would be required in each arm of the study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional, metabolic and endocrine diseases: Diabetes

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Proportion of participants who have achieved good blood pressure control defined as reaching the recommended level of <140/80.

Secondary outcome measures

Change in blood pressure from baseline, attendance at hypertension review appointments and patient satisfaction with the care received. Both measures will be assessed at 12 months post recruitment to the trial.

Overall study start date

01/03/2001

Completion date

28/02/2003

Eligibility

Key inclusion criteria

The study population will comprise all patients with type 2 diabetes on the lists of participating general practitioners who give informed consent to participate in the study.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

388 participants would be required in each arm of the study.

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2001

Date of final enrolment

28/02/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Consultant Physician
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2007		Yes	No