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Blood pressure control in diabetes in primary care

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/12/2008	Nutritional, Metabolic, Endocrine	

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
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