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Near patient testing for glycated haemoglobin

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
03/12/2008	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RBG 99X24

Study information

Scientific Title

Study objectives
A randomised controlled trial of near patient testing for glycated haemoglobin in people with diabetes mellitus in primary care.

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
1. Patients in the intervention arm will have near patient testing (NPT) for their glycated haemoglobin
2. Patients in the control arm will have normal procedure for measurement of glycated haemoglobin

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Main outcome will be the proportion of patients achieving good control. The acceptability and cost effectiveness of the NPT for glycated haemoglobin will be determined. The key measures of success will be an improvement in the number of patients having annual glycated haemoglobin measurements and improvement in glycated haemoglobin levels.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2000

Completion date
28/02/2002

Eligibility

Key inclusion criteria
Based on increasing the proportion of patients achieving good control of their HbA by 10%, from around 42%, the currently reported figure with a significance level of 5% and power of 80%, approximately 380-390 patients would be needed in each group, a study sample of 760-780.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
780

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2000

Date of final enrolment
28/02/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of General Practice and Primary Health Care
Leicester
United Kingdom
LE5 4PW

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	01/07/2006		Yes	No
Results article	acceptability and satisfaction results	01/07/2007		Yes	No