Near patient testing for glycated haemoglobin

Submission date 23/01/2004	Recruitment status No longer recruiting
Registration date 23/01/2004	Overall study status Completed
Last Edited 03/12/2008	Condition category Nutritional, Metabolic, Endocrine

[] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Kamlesh Khunti

Contact details

Department of General Practice and Primary Health Care University of Leicester Gwendolen Road Leicester United Kingdom LE5 4PW +44 (0) 116 258 4873

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

 Patients in the intervention arm will have near patient testing (NPT) for their glycated haemoglobin
 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?
<u>Results article</u>	results	01/07/2006		Yes	No
<u>Results article</u>	acceptability and satisfaction results	01/07/2007		Yes	No