

Near patient testing for glycated haemoglobin

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 03/12/2008	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

Results and Publications

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