A randomised controlled trial (RCT) to compare minimally invasive glucose monitoring devices to conventional monitoring in the management of insulin treated diabetes mellitus.

Submission date	Recruitment status	Prospectively registered
25/04/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	Condition category	Individual participant data
11/06/2009	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.ctu.mrc.ac.uk/studies/mitre.asp

Contact information

Type(s)

Scientific

Contact name

Dr Steven Hurel

Contact details

Diabetes & Endocrinology
University College London Hospitals Foundation Trust
Mortimer Street
London
United Kingdom
W1T 3AA
+44 (0)207 380 9029
s.hurel@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 01/13/03

Study information

Scientific Title

Acronym

MITRE

Study objectives

Primary Objectives 1-3, Secondary Objectives 4-7:

- 1. To compare the benefits of the GlucoWatch and CGMS Minimed on glycemic control relative to conventional monitoring and an attention control.
- 2. To assess patient acceptability and ease of use of the new technologies.
- 3. To model the long-term health benefits and costs and cost-effectiveness of these technologies.
- 4. To assess the impact of the devices on health care utilisation for diabetes related illnesses e.g. hypoglycemia, ketosis.
- 5. To assess impact of monitoring devices on patient satisfaction with care, attitudes toward diabetes and quality of life.
- 6. To assess the extent to which demographic factors (e.g. age, ethnicity) and individual differences in health cognitions influence outcome.
- 7. To assess the reliability of the glucowatch in clinical practice using available data.

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

Please note that, as of 14 January 2008, the anticipated start and end dates of this trial have been updated from 1 April 2002 and 31 March 2005 to 1 December 2002 and 31 August 2008, respectively.

Interventions:

This will be a 4 arm RCT:

Group 1. GlucoWatch

Group 2. Continuous Glucose Monitoring System (CGMS) Minimed

Group 3. Attention control with a frequency of nurse feedback sessions the same as Groups 1 and 2

Group 4. Standard care i.e. 6 monthly clinic review

Intervention Type

Device

Phase

Not Specified

Primary outcome measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/12/2002

Completion date

31/08/2008

Eligibility

Key inclusion criteria

Diabetics

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Added as of 10/09/07: Accrual target: 400; Accrual count: 404

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/12/2002

Date of final enrolment

31/08/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Diabetes & Endocrinology

London United Kingdom W1T 3AA

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/05/2009		Yes	No