ISRCTN33678610 https://doi.org/10.1186/ISRCTN33678610

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
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
11/06/2009

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

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

Contact information

Type(s)
Scientific

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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
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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