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Can a new method of monitoring improve the control of blood glucose levels in patient with Type II diabetes who have had a heart attack?

Submission date
12/06/2017

Recruitment status
No longer recruiting

Registration date
13/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a chronic condition that causes blood sugar (glucose) levels to be uncontrolled. Patients with diabetes who have had a heart attack often do worse than those without diabetes. Controlling blood sugar levels in these patients is known to improve recovery and long term quality of life. This study investigates new ways to monitor blood sugar in patients with Type 2 Diabetes who have had a heart attack. The aim of this study is to see if patients using the new way to monitor blood glucose improve overall glucose levels by keeping them in the normal range, which may improve outcome and quality of life.

Who can participate?
Adults aged 18 and older with diabetes mellitus that have had a heart attack

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group monitor their blood glucose using finger prick testing (as normal) and wear a small sensor on the back of the arm that analyses glucose levels in detail between the first day of wearing the sensor to 30 days of wearing the sensor and 76 days to 90 days of wearing the senor. The results from this sensor are for research purposes only and are not available to the participant. Those in the second group wear a similar sensor on the back of their arm for 90 days (changed every 14 days by the participant following training) and are able to access glucose results using a reader. All participants attend study visits at day 15, 30, 76 and 91 and receive final follow-up calls are made after one year. Blood tests are done at the beginning of the study and 91 days after enrollment to assess glucose levels. Participants are asked to fill in three short questionnaires at baseline and day 91 to assess the treatment.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
1.St James's University Hospital

2.Royal Hallamshire Hospital
3.Hull Royal Infirmary

When is the study starting and how long is it expected to run for?
May 2017 to April 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
34758

Study information

Scientific Title
Improving glucose control in patients with diabetes following myocardial infarction: The role of a novel glycaemia monitoring strategy

Acronym
LIBERATES

Study objectives
“The aim of this study is to see if patients using new ways to monitor blood glucose can improve overall glucose levels by keeping them in the normal range, which may improve outcome and quality of life.”

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: Atherothrombosis; UKCRC code/ Disease: Cardiovascular/ Ischaemic heart diseases, Metabolic and Endocrine/ Diabetes mellitus

Interventions
Patients who have been identified as eligible (who have had a heart attack in the last 5 days) by the treating Cardiology team are approached by a Research Nurse about the study while they are in hospital. If the patient would like to take part they are given a Patient Information Leaflet and the Research Nurse takes informed consent. They then are randomly assigned to one of two groups.

The standard group have their blood glucose monitored using finger prick testing (as normal) and wear a small sensor on the back of the arm that analyses glucose levels in detail between days 0-30 and 76-90. The results from this sensor are for research purposes only and are not be available to the participant.

The intervention group wear a similar sensor on the back of their arm for 90 days (changed every 14 days by the participant following training) and are able to access glucose results using a reader.

Both groups attend study visits at day 15, 30, 76 and 91 following enrolment (baseline) and a final follow-up call are made after one year. Blood tests are taken at baseline and day 91 and participants are asked to fill in three short questionnaires at baseline and day 91. Participants have their blood glucose results reviewed at study visits and treatment may be adjusted accordingly.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Time per day (00:00 to 23:59) spent in euglycaemia (defined as glucose ≥3.9 and ≤10.0 mmol/L) is measured using the Self-monitoring of Blood Glucose (SMBG) (Standard Arm) with continuous glucose monitoring using the Freestyle Libre Flash Glucose Monitoring System and Ambulatory Glucose Profile (AGP) between days 76 to 91 post-randomisation.

Key secondary outcome(s))
1. Time per day (00:00 to 23:59) spent in euglycaemia (≥3.9 and ≤10.0 mmol/L) is measured using AGP readings taken automatically by glucose sensor devices worn in each arm of the study between days 15-30 post-randomisation
2.Time per day (00:00 to 23:59) spent in hypoglycaemia (<3.9 mmol/L) is measured using AGP readings taken automatically by glucose sensor devices worn in each arm of the study) between days 15-30 and days 76-91 post-randomisation
3. Time per day (00:00 to 23:59) spent in hyperglycaemia (>10.0 mmol/L) is measured using AGP readings taken automatically by glucose sensor devices worn in each arm of the study between days 15-30 and 76-91 post-randomisation
4. HbA1c is measured using blood tests measuring for HbA1c readings at day 91 post-randomisation
5. Weight (Kg) is measured using kilograms at baseline and day 91 post-randomisation
6. Blood Pressure is measured using blood pressure monitors at day 91 post-randomisation
7. Health and treatment related quality of life are measured via EQ-5D-5L, Diabetes Treatment Satisfaction Questionnaire and Questionnaire and the Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire at 91 days post-randomisation
8. Cost Effectiveness is measured using a validated Health Economics model at day 91 post-randomisation
9. Adverse events measured comparing the number of adverse events reported between the two trial arms at day 91 post-randomisation

Completion date
30/04/2020

Eligibility

Key inclusion criteria

1. Patients aged ≥ 18 years
2. Type 2 Diabetes Mellitus defined as a preadmission diagnosis
3. Pre-admission treatment of hyperglycaemia with sulphonylurea and/or insulin, with or without additional hypoglycaemic agents
4. MI defined as typical symptoms of cardiac ischaemia associated with a typical rise in troponin levels using the 99th percentile threshold cut-off as per the Third Universal Definition of MI. Patients with either ST-elevation MI (STEMI) or non-ST elevation MI (NSTEMI) are eligible to participate.
5. Patient has provided written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
141

Key exclusion criteria
1. Solely diet-controlled T2DM preadmission
2. Patient has active malignancy other than localised squamous cell or basal cell skin carcinoma.
3. Patient who has a current pacemaker fitted, known to be pregnant or requiring dialysis.
4. Patient is unable to follow study instructions or considered unsuitable for trial participation at the discretion of the treating clinician/nurse.
5. Patient previously participated in the LIBERATES trial

Date of first enrolment
01/08/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
Leeds Teaching Hospital NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Hallamshire Hospital
Sheffield Teaching Hospital NHS Trust
8 Beech Hill Road
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United Kingdom
S10 2JF

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospitals NHS Trust
Anlaby Road
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Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2023	11/07/2023	Yes	No
Protocol article	protocol	01/05/2020	23/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes