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Improving care for diabetic patients on dialysis: can using a new device to identify risk periods of 'high' and 'low' blood sugars in both hospital and home dialysis patients

Submission date
07/09/2016

Recruitment status
No longer recruiting

Registration date
19/09/2016

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. When the kidneys fail, they stop cleaning the blood, leading to the build-up of harmful waste products. Haemodialysis is one of the most common treatments for kidney failure. It involves diverting the blood into an external machine so that it can be cleaned, before being returned to the body. Diabetes is one of the main causes of kidney failure and the number of people who have diabetes is increasing. This is because blood sugar levels in diabetics swing between high and low, leading to long-term damage to the body. Altogether about 1/3 of people on haemodialysis in the UK have diabetes. Although diabetes tests and treatments are well researched in a person with healthy kidneys, little is understood about what happens when a diabetic person needs haemodialysis. This project aims to uses new technology called continuous glucose (blood sugar) monitoring to learn more about the changes in blood sugar in diabetic patients with kidney failure when they are on, and around, their haemodialysis.

Who can participate?
Diabetic adults with kidney failure, who go to a dialysis centre three times per week, undergo shorter but more frequent haemodialysis at home, and those who are going from one to the other.

What does the study involve?
Participants are visited in the dialysis unit or at home to have a glucose sensor fitted. This involves the sensor being placed on the back of the arm. It has a disc (3.5cm x 0.5cm) that will stick to the skin and thin flexible sterile fibre (5mm long) that is inserted just below the skin. The sensor then remains in place for 14 days and measures the glucose level in the tissue under the skin continuously. During this time, participants are also asked to fill in an activity diary and continue as normal.

What are the possible benefits and risks of participating?
Participants benefit from finding out information about their blood sugar control which was previously unknown. The safety of the continuous glucose monitors has been assessed by the manufacturer. Infections when the device is inserted into the skin are rare, but participants are closely monitored for this.

Where is the study run from?
Wessex Kidney Centre (UK)

When is the study starting and how long is it expected to run for?
March 2015 to July 2018

Who is funding the study?
1. Abbott Diabetes Care (UK)
2. Portsmouth Hospitals NHS Trust (UK)

Who is the main contact?
Dr Katey Atkins

Contact information

Type(s)
Public

Contact name
Dr Katey Flowers

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHT/2016/83

Study information

Scientific Title
Observational Study of Glucose Variability in insulin-treated diabetic individuals with established renal failure (ERF)

Acronym
DRIVE - HD Study

Study objectives
Using flash glucose monitoring to produce ambulatory glucose profiles in diabetic individuals with established renal failure (ERF) can identify unacceptable (and potentially dangerous) features of glycaemic control, such as large excursions or prolonged hypo- or hyper-glycaemia, that have gone unrecognised by the patient and begin to build a body of data illustrating the relationships between insulin prescription, dialysis and serum glucose to be able to improve individualised care and, in particular, patient safety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority, 02/03/2017, IRAS number: 212219, REC ref: 17/LO/0131

Study design
Single-centre cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Renal failure

Interventions
Interventions as of 29/12/2016:
Patients who routinely receive either in-centre haemodialysis or home haemodialysis will be enrolled and require a total of 3 visits. The first will be to provide information regarding the study and answer initial question. The second will be to recruit them formally and sign a consent form, baseline data will be collected, a sensor will be applied, their SMBG will be downloaded (via Diasend) and a diary (insulin/food/exercise) will be provided. The sensor will remain in place for 14 day (the observation period); over this time they will be asked to complete the provided diary. The third visits will be remove the sensor, collect the diary and re-download the SMBG data. They will they complete a validated questionnaire on confidence in diabetes self-management (devised by the Stanford patient education centre). Selected participants (10 in total) will undertake a semi-structured interview to probe the educational process regarding managing their chronic conditions.
Some patients enrolled in the study will be electing to swap from in-centre to home haemodialysis. They will undergo the above process on each dialysis modality; so have the sensor on and observational period over 14 days undertaken twice.
There will be no other direct follow up from this study protocol, however all participants will receive a summary of the finding of the study.

Original interventions:
Patients who routinely receive either in-centre haemodialysis or home haemodialysis will be enrolled and require a total of 3 visits. The first will be to provide information regarding the study and answer initial question. The second will be to recruit them formally and sign a consent form, baseline data will be collected, a sensor will be applied, their SMBG will be downloaded (via Diasend) and a diary (insulin/food/exercise) will be provided. The sensor will remain in place for 14 day (the observation period); over this time they will be asked to complete the provided diary. The third visits will be remove the sensor, collect the diary and re-download the SMBG data. If the first visit is considered to be week 1, the second is on week 2 and third is on week 4. The sensor will be screened for a set of features deemed unacceptable to leave without intervention. These features have been defined by a consultant diabetologist and the participant will be contacted directly should features warranting an urgent insulin therapy adjustment be identified - this will occur within 5 working days following the removal of the sensor
Some patients enrolled in the study will be electing to swap from in-centre to home haemodialysis. They will undergo the above process on each dialysis modality; so have the sensor on and observational period over 14 days undertaken twice. If after the first planned sensor (on in-centre haemodialysis) unacceptable glucose results are found and a insulin adjustment is required we will ask these participants to have a second sensor while on in-centre prior to the swap of dialysis, therefore these participants will have three sensors and three 14-day observational periods.
There will be no other direct follow up from this study protocol, however all participants will receive a copy of their AGP with an explanation of their results. This will also go to their GP / diabetes hospital consultant.

Intervention Type

Device

Phase
Not Specified

Primary outcome measure
Primary outcome measure as of 29/12/2016:
Ambulatory glucose profile as generated by 14 days of interstitial glucose monitoring.

Original primary outcome measure:
Overall glycaemic variability is determined using interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period.

Secondary outcome measures
Secondary outcome measures as of 30/12/2016:
1. Analysis of the ambulatory glucose profile during day-time hours, night-time hours, pre-meal period, postprandial period, pre-dialysis (6 hour window), post-dialysis (6 hour window and 12 hour window) and hour by hour across the day
2. Analysis of the area under the curve of the ambulatory glucose profile spent hypoglycaemic (<3.9mmol/l, <3.3mmol/l and <3.0mmol/l), euglycaemic (4-10mmol/l) and hyperglycaemic (>10mmol/l and >15mmol/l)
3. Analysis of discrete episodes of the ambulatory glucose profile hypoglycaemic (<3.9mmol/l, <3.3mmol/l and <3.0mmol/l), euglycaemic (4-10mmol/l) and hyperglycaemic (>10mmol/l and >15mmol/l)
4. Score from Stanford patient education centre questionnaire at sensor removal
5. Relationship between dialysis prescriptions and insulin regimes to the overall glycaemic variability is determined using interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period
6. Relationship between glycaemic variability and demographic data (details of past medical, socioeconomic and educational history) is determined through interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period and participant interviews

Original secondary outcome measures:
The following secondary outcomes are measured during 14 day continuous glucose monitoring
1. Time during 14 day continuous glucose monitoring spent within glucose target range (4-10mmol/L)
2. Time during 14 day continuous glucose monitoring spent above target range > 10mmol/L
3. During 14 day continuous glucose monitoring number of discrete episodes > 10mmol/L
4. Time during 14 day continuous glucose monitoring spent above target range > 15mmol/L
5. During 14 day continuous glucose monitoring number of discrete episodes > 15mmol/L
6. Time during 14 day continuous glucose monitoring spent below target range <3.9mmol/L (70mg/dl)
7. During 14 day continuous glucose monitoring number of discrete episodes <3.9mmol/L
8. Time during 14 day continuous glucose monitoring spent below <3.3mmol/L (60mg/dl)
9. Time during 14 day continuous glucose monitoring spent below <3.0mmol/L
10. During 14 day continuous glucose monitoring number of discrete episodes <3.0mmol/L

Additional clinical outcomes:
1. Glycaemic variability over the day, night, pre-meals, post-prandial, pre-dialysis (the 6 hours before dialysis), post-dialysis (the 6 hours and 12 hours after dialysis) and hourly across the

modal day is determined using interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period
2. Relationship between dialysis prescriptions and insulin regimes to the overall glycaemic variability is determined using interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period
3. Relationship between glycaemic variability and demographic data (details of past medical, socioeconomic and educational history) is determined through interstitial glucose measurements collected by a continuous glucose monitor over a 14 day period and participant interviews

Overall study start date
04/04/2016

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Male or Female aged 18 years or above
2. Diagnosis of Diabetes Mellitus requiring insulin therapy
3. On Renal Replacement Therapy for a minimum of 3 months
4. Have downloadable SGBM devise already in use

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Total final enrolment
89

Key exclusion criteria
1. Acute prescription (within 2 weeks) of medication that may increase or decrease serum glucose
2. Planned change of renal replacement modality during study period
3. Co-enrolment in other studies that provided therapies or interventions that may affect glycaemia control
4. Unable to provide informed consent

Added 29/12/2016:
5. Planned x-ray, computed tomography (CT) scan, magnetic resonance imaging (MRI) or high-frequency electrical heat (diathermy) treatment during the study period

Date of first enrolment
02/01/2017

Date of final enrolment
03/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wessex Kidney Centre
Queen Alexandra Hospital
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Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

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Research and Innovation
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/009fk3b63

Funder(s)

Funder type
Research organisation

Funder Name
Abbott Diabetes Care

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Portsmouth Hospitals NHS Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal around one year after overall trial end date. Data from this study will also be submitted for the postgraduate award of an MD with the University of Portsmouth.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Katey Flowers at Katey.Flowers@porthosp.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	26/07/2023	No	No