ISRCTN10603608 https://doi.org/10.1186/ISRCTN10603608

Determining the amount of time with low glucose in people using premixed (biphasic) insulin

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
22/05/2019

Overall study status
Completed

Last Edited
01/07/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background & study aims
Diabetes is a lifelong condition where the amount of sugar in the blood is too high. The aim of this pilot study is to collect glucose data using the FreeStyle Libre Pro Flash Glucose Monitoring System from adults with type 2 diabetes using pre-mixed (biphasic) insulin.

Who can participate?
Patients aged 18 and over with type 2 diabetes using pre-mixed (biphasic) insulin and an HbA1c less than 7.5% (58 mmol/mol).

What does the study involve?
Participants will wear two Sensors for up to 14 days (glucose data is not visible during this time). Participants will return to the clinic for Visit 2 where the Sensors will be removed, and data uploaded.

What are the possible benefits & risks of participating?
There is no direct benefit to the participant by taking part in this study. The only risks associated with the study are from obtaining venous blood samples, these are small but could include pain, bruising, local infection and fainting. Data collected may be used to support future pivotal clinical study designs in this population.

Where is the study run from?
1. Royal Derby Hospital, Derby
2. Royal Berkshire Hospital, Reading
3. Royal Blackburn Hospital, Blackburn
4. Ninewells Hospital, Dundee
5. Royal Infirmary of Edinburgh, Edinburgh
6. Hathaway Medical Centre, Chippenham
7. Kiltearn Medical Centre, Nantwich
8. Ashfields Primary Care Centre, Sandbach
9. Claremont Medial Practice, Exmouth

10. Albany House Medical Centre, Wellingborough
11. Eynsham Medical Group, Eynsham
12. The Adam Practice, Hamworthy

When is the study starting and how long is it expected to run for?
28/05/2019 to 31/07/2019

Who is funding the study?
The study is funded by Abbott Diabetes Care Ltd

Who is the main contact?
Dr Pamela Reid
Pamela.Reid@abbott.com

Study website
N/A

Contact information

Type(s)
Public

Contact name
Dr Pamela Reid

Contact details
Abbott Diabetes Care
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ADC-UK-PMS-19040

Study information

Scientific Title

Pilot study to determine Time in HYpoglycaemia when using pre-MixEd (biphasic) insulin

Acronym
THYME

Study objectives
This pilot study is being conducted to determine the amount of time spent in low glucose or hypoglycaemia (less than 3.9 mmol/L [70 mg/dL]) by people with type 2 diabetes when using pre-mixed (biphasic) insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2019, NRES Committee: South West – Cornwall and Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 0207 104 8048; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: 19/SW/0086.

Study design
Prospective, multi-centre, single arm, pilot study in both hospital and GP practice settings.

Primary study design
Interventional

Secondary study design
Single-arm pilot study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Participants will wear two FreeStyle Libre Pro Flash Glucose Monitoring Sensors for up to 14 days. There is no follow-up period unless the participant experiences an unanticipated adverse device effect (ADE).

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Time in hypoglycaemia (<3.9 mmol/L [70 mg/dL]), measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the two-week study duration.

Secondary outcome measures
Other glycaemic measures such as time in range (3.9-10.0 mmol/L [70-180 mg/dL]), measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the two-week study duration.

Overall study start date
01/01/2019

Completion date
07/08/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over.
2. Type 2 diabetes treated with pre-mixed (biphasic) insulin for at least 6 months prior to study enrolment.
3. Most recent HbA1c less than 7.5% (58 mmol/mol), recorded in medical notes in last 12 months.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
43

Key exclusion criteria
1. Currently prescribed animal insulin.
2. Concomitant disease or condition that may compromise patient safety including and not limited to; cystic fibrosis, severe mental illness, a diagnosed or suspected eating disorder or any uncontrolled long term medical condition.
3. Has a pacemaker or any other neurostimulators.
4. Currently receiving dialysis treatment or planning to receive dialysis during the study.
5. Women who are pregnant, plan to become pregnant or become pregnant during the study.
6. Participating in another study of a glucose monitoring device or drug that could affect glucose

measurements or management.
7. Known (or suspected) allergy to medical grade adhesives.
8. In the investigator’s opinion, unsuitable to participate due to any other cause/reason.

Date of first enrolment
28/05/2019

Date of final enrolment
24/07/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Royal Derby Hospital
United Kingdom
DE22 3NE

Study participating centre
Royal Berkshire Hospital
United Kingdom
RG1 5AN

Study participating centre
Royal Blackburn Hospital
United Kingdom
BB2 3HH

Study participating centre
Ninewells Hospital
United Kingdom
DD1 9SY

Study participating centre

Royal Infirmary of Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Hathaway Medical Centre
United Kingdom
SN14 6GT

Study participating centre
Kiltearn Medical Centre
United Kingdom
CW5 5NX

Study participating centre
Ashfields Primary Care Centre
United Kingdom
CW11 1EQ

Study participating centre
Claremont Medial Practice
United Kingdom
EX8 2JF

Study participating centre
Albany House Medical Centre
United Kingdom
NN8 4RW

Study participating centre
Eynsham Medical Group
United Kingdom
OX29 4QB

Study participating centre

The Adam Practice
United Kingdom
BH15 4JQ

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Sponsor details
Range Road
Witney
United Kingdom
OX29 0YL
+44 1993 863164
Joe.Bugler@abbott.com

Sponsor type
Industry

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. Estimated timeline is one year from trial end date.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Pamela Reid.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/09/2021	01/07/2022	Yes	No
HRA research summary			28/06/2023	No	No