

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

Submission date 03/05/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/07/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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. Kiltarn Medical Centre, Nantwich
8. Ashfields Primary Care Centre, Sandbach
9. Claremont Medical 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