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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registeredProtocol		
03/05/2019				
Registration date	Overall study status	Statistical analysis plan		
22/05/2019	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/07/2022	Nutritional, Metabolic, Endocrine			

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

Contact information

Type(s)

Public

Contact name

Dr Pamela Reid

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 premixed (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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Scotland

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes