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Determining variation in glucose levels in people with impaired glucose tolerance (prediabetes)

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
22/05/2019

Overall study status
Completed

Last Edited
10/06/2024

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
The number of people with diabetes continues to rise throughout the world. In addition, there has been a similar rise in impaired glucose tolerance or prediabetes, which is a risk factor for developing type 2 diabetes. The aim of this pilot study is to collect glucose data using the FreeStyle Libre Pro Flash Glucose Monitoring System from adults with impaired glucose tolerance.

Who can participate?
Patients aged 18 and over with an HbA1c of 5.7-6.4% (39-47 mmol/mol).

What does the study involve?
Participants will wear two FreeStyle Libre Pro Sensors for up to 14 days (glucose data is not visible during this time). Participants will also be supplied with a fitness tracker and a tablet; an app will be pre-installed on the tablet and participants will be requested to record dietary intake for three days.
Participants will return to clinic for Sensor removal and data upload (Sensor and tracker), they will then wear a FreeStyle Libre Sensor for up to 14 days (glucose data will be visible during this time). Participants will be requested to complete a questionnaire at the end of the study.

What are the possible benefits & risks of participating?
The study gives participants with impaired glucose tolerance the opportunity to experience sensor technology using the FreeStyle Libre Pro and FreeStyle Libre Systems. 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 inform future pivotal clinical study designs in this population.

Where is the study run from?
1. Hathaway Medical Centre, Chippenham
2. Claremont Medial Practice, Exmouth
3. Albany House Medical Centre, Wellingborough

4. The Adam Practice, Hamworthy
5. Atherstone Surgery, Atherstone

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

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-19041

Study information

Scientific Title
A pilot study to determine glycaemic variability in people with impaired glucose tolerance (prediabetes)

Acronym
SAGE

Study objectives
This pilot study is being conducted to determine the amount of glycaemic variability (measured by %CV glucose) in people with impaired glucose tolerance (prediabetes).

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; +44 (0)207 104 8048; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: 19/SW/0087

Study design
Prospective multi-centre single-arm pilot study

Primary study design
Interventional

Secondary study design
Single-arm pilot study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Impaired glucose tolerance

Interventions
Participants will wear two FreeStyle Libre Pro Flash Glucose Monitoring Sensors for up to 14 days, followed by FreeStyle Libre for up to 14 days. During the Libre Pro sensor wear, participants will wear a fitness tracker (throughout the two weeks) and record dietary intake (for three days).

There is no follow-up period unless the participant experiences an unanticipated adverse device effect (ADE).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FreeStyle Libre Pro Flash Glucose Monitoring Sensor, FreeStyle Libre

Primary outcome measure
Glycaemic variability (%CV glucose), measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the first two-weeks of the study.

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 first two-weeks of the study.

Overall study start date
01/01/2019

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over.
2. Most recent HbA1c 5.7-6.4% (39-47 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. Recorded diagnosis of diabetes.
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
27/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hathaway Medical Centre
United Kingdom
SN14 6GT

Study participating centre
Claremont Medial Practice
United Kingdom
EX8 2JF

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

Study participating centre
The Adam Practice
United Kingdom
BH15 4JQ

Study participating centre
Atherstone Surgery
United Kingdom
CV9 1EU

Sponsor information

Organisation
Abbott Diabetes Care Ltd

Sponsor details
Range Road
Witney
United Kingdom
OX29 0YL
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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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/06/2020	01/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Abstract results		25/08/2020	10/06/2024	No	No