ISRCTN15977623 https://doi.org/10.1186/ISRCTN15977623

Testing a non-invasive smartphone application to predict sugar levels in the blood

Submission date
31/05/2022

Recruitment status
No longer recruiting

Registration date
27/06/2022

Overall study status
Completed

Last Edited
20/06/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The key to managing and living well with diabetes involves early diagnosis and monitoring of glucose (blood sugar) control. Traditional self-monitoring of blood glucose (SMBG) via finger-prick testing can help patients to maintain their glucose levels within the appropriate range. However, we know each SMBG test requires a single-use test strip and lancet, conferring a significant economic burden on healthcare systems and patients. Additionally, the discomfort of SMBG can result in reduced compliance with monitoring. A non-invasive glucose monitoring device (NIGMD) has the potential to achieve efficiency savings and can reduce physical and psychological barriers to testing. The Bioepic Glucose Monitoring System is a NIGDM that utilises a video trace of blood flow in the user's fingertip (recorded by a smartphone camera) to quantify certain aspects of the user's pulse and uses artificial intelligence (AI) to predict the blood glucose level. This AI has been trained using SMBG measurements from individuals with and without diabetes.

Who can participate?
Adults with type 2 diabetes

What does the study involve?
The purpose of this study is to test the AI-predicted blood glucose level derived from the Bioepic system in individuals with non-insulin-treated Type 2 Diabetes and compare the readings with those from SMBG. The Bioepic system glucose reading is recorded via a pre-downloaded App on a smartphone, by placing a fingertip over the smartphone camera lens for 30 seconds. An SMBG reading is also recorded to create a 'matched pair'. Participants will not have access to the glucose value recorded by the App. The study would be undertaken in two parts. One part would involve participants recording matched pairs at home over a 30-day period. The other part of the study would involve participants taking matched pair samples at a study site before and after a set carbohydrate meal. These matched pairs will be compared to assess the accuracy of the Bioepic system against accepted standards.

What are the possible benefits and risks of participating?
The study benefits are that this is a non-invasive method to measure glucose levels
There are no known risks to participants

Where is the study run from?
Southern Diabetes Medical Services

When is the study starting and how long is it expected to run for?
August 2020 to December 2022

Who is funding the study?
Bioepic Ltd (UK)

Who is the main contact?
Dr Richard Wood (scientific)
richard@ennehealth.com

Contact information

Type(s)
Scientific

Contact name
Dr Richard Wood

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Additional identifiers

Integrated Research Application System (IRAS)
296787

Protocol serial number
BIOAPP1010

Study information

Scientific Title
Intermediate type 2 diabetes trial

Acronym
IT2DT

Study objectives
The aim of this study is to compare the predicted blood glucose levels derived from the Bioepic non-invasive Smartphone application compared with the glucose values measured using a blood

glucometer from the blood drawn from a finger prick test. This aim will test the hypothesis that the percentage of individual glucose values measured by the Bioepic Smartphone Application compared with capillary glucometer readings falling within zones A and B of the Consensus error grid will meet the minimum criteria for acceptable system accuracy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/07/2021, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8379; frenchay.rec@hra.nhs.uk), ref: 1/SW/0030

Primary study design
Observational

Study design
Observational methodological comparison study

Study type(s)
Diagnostic

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

Interventions
The Bioepic system is a non-invasive technology that is designed to predict blood glucose levels, using artificial intelligence, from a 30-second fingertip video recorded by the camera of a smartphone with Bioepic's proprietary App. The aim of this study is to compare the blood glucose levels derived from the Bioepic App with the glucose values measured by a standard blood glucometer via a finger-prick test to demonstrate the accuracy of the Bioepic system.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Estimated blood glucose levels measured using the Bioepic System, a pre-loaded smartphone App (Enne Health) that characterises an approximation of blood glucose by taking a Photoplethysmography (PPG) video of the fingertip, falling within zones A and B of the Consensus error grid and therefore meeting the minimum criteria for acceptable system accuracy in 100 paired glucose readings taken at home over a 30 day period (3-6 readings per day) plus 6 readings on the active study day, 15 minutes apart.

To compare the blood glucose levels derived from the Bioepic App with the glucose values measured by a standard blood glucometer via a finger-prick test the simultaneous App glucose and the glucometer result are paired to facilitate analysis. The accuracy of the App values will be assessed against the internationally agreed standard according to the Consensus error grid, aiming to demonstrate that at least 99% of App values will lie within zones A and B of the

Consensus error grid, which would be in line with requirements for all blood glucose monitors for patient use.

Key secondary outcome(s)
The percentage of predicted glucose levels from the Bioepic App System meeting the minimum criteria for acceptable system accuracy when grouped by certain criteria:
1. Glucose level, as measured by 100 paired blood glucose readings taken at home over a 30 day period (3-6 readings per day) plus 6 readings on the active study day, 15 minutes apart
2. Glycated haemoglobin (HbA1c) level, as measured in mmol/mol by laboratory immunoassay within the previous 3 months of commencing the study
3. Demographics – including weight, age, as measured in Kg by standard scales at the beginning of the study
4. Daily activity and other participant daily log conditions, as measured by patient recall (light, medium or heavy exercise) at the beginning of the study

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Type 2 diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Body mass index < 18.5 kg/m2
2. Pregnancy or lactating
3. Participation in any clinical study during the previous 2 months
4. Any other condition that in the opinion of the investigator would interfere with the evaluation of the study results or constitute a health risk for the participant
5. Any medication that in the opinion of the investigator would interfere with the evaluation of the study results
6. Recreational or illicit drug intake
7. Individuals who fail to utilise the Smartphone App appropriately
8. Aversion to the sight of blood
9. Severe coronary heart disease
10. Participants with known uncontrolled hypertension (i.e. >160mmHg systolic or >95 mmHg diastolic)
11. Severe renal impairment (eGFR<15ml/min)

Date of first enrolment
20/04/2022

Date of final enrolment
20/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southern Diabetes Medical Services
Carnac Place
Cams Hall Estate
Fareham
United Kingdom
PO16 8UY

Sponsor information

Organisation
Bioepic Ltd

Funder(s)

Funder type
Industry

Funder Name
Bioepic Ltd

Results and Publications

Individual participant data (IPD) sharing plan
Stored in a non-publicly available repository, which is a cloud-based storage platform. The repository stores the neural network-based glucose estimates from pulse plethysmography that are incorporated directly into a diabetes log with paired glucometer readings and also allows the

individual to record activities, meals etc., and all other collated data that are stored anonymously.

IPD sharing plan summary

Stored in non-publicly available repository