ISRCTN66273796 https://doi.org/10.1186/ISRCTN66273796

Study of the accuracy of a home oral glucose tolerance test kit

Submission date
07/03/2023

Recruitment status
No longer recruiting

Registration date
16/05/2023

Overall study status
Completed

Last Edited
24/03/2023

Condition category
Pregnancy and Childbirth

[ ] 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 GTT@home oral glucose tolerance test device is an electronic device that has the potential to enable patients to perform an oral glucose tolerance test (OGTT) from home. Gestational diabetes mellitus (GDM) is a common metabolic disorder occurring in up to 10% of pregnancies in the western world. Most women with GDM are asymptomatic and therefore it is important to screen, diagnose and manage the condition as it is associated with an increased risk of maternal and perinatal complications. In the UK, women with a high risk of GDM are offered a 75 g glucose tolerance test (OGTT) at 24-28 weeks gestation. Undertaking an OGTT without bringing pregnant mothers into the clinical setting or keeping them in clinic for extended periods would be an attractive option, especially if the test could be performed in the comfort of the home. In non-pregnant women the GTT@home device has been previously shown to be easy to use, reliable and demonstrate excellent agreement with the results obtained from laboratory analysers. As part of the development programme it is now necessary to establish how results from this device compare with results obtained conventionally from an oral glucose tolerance test in women at risk of GDM.

Who can participate?
Women aged 18 years and over with a body mass index (BMI) above 20 kg/m², a previous macrosomic (larger than average) baby, previous gestational diabetes, a family history of diabetes or of an ethnicity with a high prevalence of diabetes

What does the study involve?
Glucose concentrations during an oral glucose tolerance test will be tested with fresh blood samples from women at risk of GDM and compared to routine laboratory glucose concentrations.

What are the possible benefits and risks of participating?
There will be no benefits to participants, however, there may be benefits in the future to patients who require an oral glucose tolerance test. There may be some pain during blood sampling with possible bruising, swelling or irritation.

Where is the study run from?
Neath Port Talbot Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2022 to October 2023

Who is funding the study?
Digostics Ltd (UK)

Who is the main contact?
Prof. S Luzio, s.luzio@swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Steve Luzio

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Additional identifiers

Integrated Research Application System (IRAS)
312243

Protocol serial number
1.0

Study information

Scientific Title
Study of the accuracy of the GTT@home oral glucose tolerance test kit

Study objectives
To compare the accuracy of the GTT@home device to a laboratory reference method

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 14/07/2022, Wales Research Ethics Committee 6 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; UK; +44 (0)2922 940910, +44 (0) 2922 940954, +44 (0)2922 941090; Wales.REC6@wales.nhs.uk), ref: 22/WA/0153

Study design
Single-centre interventional study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
A total of 65 women who meet the inclusion/exclusion criteria will have a glucose tolerance test. Fingerprick blood capillary blood samples will be measured using the GTT@home device. Venous blood samples will be measured using a routine laboratory analyser.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GTT@home

Primary outcome(s)
Accuracy measured by comparison of the categories of normal glucose tolerance and glucose intolerance using venous and capillary blood glucose readings at fasting and 2 hours

Key secondary outcome(s))
1. Sensitivity measured by comparison of the categories of normal glucose tolerance and glucose intolerance using venous and capillary blood glucose readings at fasting and 2 hours
2. Specificity measured by comparison of the categories of normal glucose tolerance and glucose intolerance using venous and capillary blood glucose readings at fasting and 2 hours

Completion date
31/10/2023

Eligibility

Key inclusion criteria

1. Female
2. Age greater than or equal to 18 years
3. BMI above 20 kg/m²
4. Previous macrosomic baby weighing greater than or equal to 4.5 kg or the 90th centile
5. Previous gestational diabetes
6. Family history of diabetes (first-degree relative with diabetes)
7. An ethnicity with a high prevalence of diabetes
8. Written, signed, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Unable or unwilling to sign informed consent

Date of first enrolment
08/03/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Neath Port Talbot Hospital
Baglan Way
Port Talbot
United Kingdom
SA12 7BX

Sponsor information

Organisation
Digostics Ltd

Funder(s)

Funder type
Industry

Funder Name
Digostics Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Prof. S Luzio (s.luzio@swansea.ac.uk)

The type of data that will be shared: Demographic data and blood glucose concentrations
Dates of availability: Following publication of results paper (approx. April 2024)
Whether consent from participants was required and obtained: Written informed consent was obtained from participants
Comments on data anonymization: All data will be anonymised and data will only be identified using a participant study number

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No