

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

Submission date 07/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/05/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/03/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number
312243

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.0, IRAS 312243

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

09/01/2022

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

65

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

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Sponsor details

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Sponsor type

Industry

Website

<https://digostics.com>

Funder(s)

Funder type

Industry

Funder Name
Digostics Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/04/2024

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