

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

<b>Submission date</b> 07/03/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/03/2023	<b>Condition category</b> 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/m<sup>2</sup>, 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

**ORCID ID**  
<http://orcid.org/0000-0002-7206-6530>

**Contact details**  
Diabetes Research Group  
Grove Building  
Medical School  
Swansea University  
Singleton Park  
Swansea  
United Kingdom  
SA28PP  
+44 (0)1792295078  
s.luzio@swansea.ac.uk

## 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/m<sup>2</sup>
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

Digostics Ltd

### Sponsor details

Harwell Innovation Centre

Curie Avenue

Didcot

England

United Kingdom

OX11 0OG

+44 (0)330 113 9145

dd@digostics.com

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No