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Evaluation of an electronic Oral Glucose Tolerance Test Kit (eOGTTK)

Submission date
18/04/2012

Recruitment status
No longer recruiting

Registration date
27/04/2012

Overall study status
Completed

Last Edited
23/10/2013

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In routine clinical practice, the most accurate way to diagnose diabetes is by conducting an Oral Glucose Tolerance Test (OGTT). An OGTT is conducted in a clinical setting (hospital or GP surgery) and involves taking blood from a vein before and after consumption of a standard sugary drink. The blood samples are sent to a laboratory for measurement of the levels of sugar (glucose) in the blood. This test can also detect changes in blood sugar levels before diabetes develops (pre-diabetes).

This study evaluated a new electronic OGTT kit that measured the level of sugar in fingerprick blood samples and was designed to be used by untrained individuals in their home. The study investigated whether the kit produced accurate and repeatable blood sugar measurements, whether participants were able to use the kit unaided, and what their feelings were about performing the test themselves.

Who can participate?
The study involved 30 participants, of whom 12 had previously diagnosed type 2 diabetes (stable for the last 3 months using diet or metformin only), 18 did not have known diabetes. The participants could have been male or female and were aged 18 or over.

What does the study involve?
Participants were asked to use the electronic OGTT kit on six occasions. The kit used fingerprick blood samples and did not require any laboratory involvement or trained personnel.

The electronic OGTT kit was assessed in 3 different settings:
1. Two home-based (and unobserved) tests
2. Two clinic-based and observed tests (preferably without any nurse intervention)
3. Two clinic-based and nurse-led tests

During the two nurse-led visits, venous blood samples for laboratory measurement of sugar were taken in tandem with the fingerprick blood samples. No drugs (oral, topical or injected) were being tested in this study.

What are the possible benefits and risks of participating?
There was no direct benefit to the participant from this study. The results of this study may provide valuable information about the future use of the electronic OGTT kit by the general public. This knowledge may be used to help others by enabling widespread screening of individuals in regions with limited access to clinical staff and laboratory resources. In the unlikely event that participants had previously unrecognized impaired glucose tolerance or diabetes this would have been detected so that treatment could be commenced at an earlier stage to give greater benefits. Some people may have felt nausea if they consumed the glucose drink too quickly. Some people may have experienced sore fingers after the finger pricks. Occasionally there may have been local bruising as a result of blood drawn from the vein.

Where is the study run from?
Clinical Research Unit at the Oxford Centre for Diabetes (Oxford, UK).

When is the study starting and how long is it expected to run for?
The first participant was recruited in April 2011 and the last visit took place in July 2011.

Who is funding the study?
Novartis Pharma AG (Basel, Switzerland).

Who is the main contact?
Prof M. Angelyn Bethel
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Study website
http://www.dtu.ox.ac.uk/trg/index.php

Contact information

Type(s)
Scientific

Contact name
Dr M. Angelyn Bethel

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TRG 10/02

Study information

Scientific Title
Evaluation of an electronic Oral Glucose Tolerance Test Kit: a randomized crossover study

Acronym
eOGTTK

Study objectives
The study assessed the reliability, repeatability, and user acceptability of a novel electronic Oral Glucose Tolerance Test Kit (eOGTTK) that guided untrained individuals to perform an oral glucose tolerance test in a home setting using capillary blood samples.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East London Research Ethics Committee, 15 March 2011, ref: 10/H0808/164

Study design
Randomized crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes (type 2)

Interventions
Participants used the eOGTTK on six occasions in three settings:
1. Two home based (and unobserved) tests
2. Two clinic based and observed tests (preferably without any nurse intervention)

3. Two clinic based and nurse-led tests
During the two nurse-led visits, venous blood samples for a standard laboratory OGTT were collected at the same time. Tests were scheduled between 2 and 7 days apart, resulting in a maximum duration of observation up to 7 weeks. Focus groups to assess user acceptability were scheduled within 4 weeks of the last test.

Samples from the 0 and 120 minute time points of the eOGTTK tests were compared to asses the degree of variation in different settings (repeatability) and the degree of variation (reproducibility) within each setting. Samples from the 0 and 120 minute time points of the eOGTTK test and the laboratory test were compared to evaluate the accuracy of the eOGTTK values.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To evaluate the precision of the eOGTTK by assessing:
1. Repeatability: the degree of variation when assessed in different settings
2. Reproducibility: the degree of variation within each setting

Secondary outcome measures
1. To evaluate the user acceptability of the eOGTTK through the use of a validated device satisfaction questionnaire and focus groups
2. To investigate any possible training effects with repeated eOGTTK use
3. To evaluate the accuracy of the eOGTTK 0 and 120 values compared with laboratory measured venous plasma glucose values

Overall study start date
01/04/2011

Completion date
06/07/2011

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Had adequate vision and reading comprehension to follow the electronic OGTT kit instructions in English
4. Patients with type 2 diabetes were:
4.1. Treated with diet alone or with metformin monotherapy
4.2. Had stable therapy for at least 3 months prior to study enrollment or
5. Individuals without diagnosed diabetes had no prior experience of an OGTT or any tests which involved finger-pricking

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 30

Key exclusion criteria
1. Pregnancy or planned pregnancy during the study period
2. Participant taking drugs that may affect glucose levels
3. History or current evidence of any condition, therapy, laboratory abnormality, or other circumstance which, in the opinion of the investigator, posed an unacceptable risk to the individual, confounded the results of the study, or was likely to interfere with the individuals participation of the full duration of the trial

Date of first enrolment
01/04/2011

Date of final enrolment
06/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Diabetes Trials Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Novartis Pharma AG (Switzerland)

Sponsor details
Lichstrasse 35
Basel
Switzerland
4056

Sponsor type
Industry

Website
http://www.novartis.com/

ROR
https://ror.org/02f9zrr09

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma AG (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Also available on the Oxford University Research Archive:	01/06/2013		Yes	No
Results article	results	01/06/2013		Yes	No