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Study to measure how well the Tensortip Combo Glucometer can measure blood glucose with finger-pricks

Submission date
27/03/2018

Recruitment status
No longer recruiting

Registration date
24/05/2018

Overall study status
Completed

Last Edited
06/11/2019

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
The aim of the study is to explore how accurately the two methods of the new TensorTip blood glucose meter (with and without the need of a finger prick) can measure blood glucose when compared to a laboratory test method. The meter should be good enough to meet the criteria required for approval by regulatory agencies in Europe (EMA) and in the US (FDA).

Who can participate?
This study is open for any adult patient (male and female, aged >18 years) with type 1 or type 2 diabetes and also for male and female healthy volunteers.

What does the study involve?
The participants will perform two visits. In the first visit, they will receive training how to calibrate the pain-free optical component of the TensorTip CoG device by means of several readings in parallel to the common measurement component, which requires a finger prick. After that they will go home and perform the calibration within the next 7 to 10 days. At the second visit, the participants will do a test at the site to check their actual blood glucose. Based on the result, the doctor will ask them to either do the comparison experiment right away or to change their blood sugar under medical supervision by either food uptake or insulin injection. During the experiment, blood glucose will be tested at one timepoint with three methods:
1. the YSI laboratory reference device (baseline measurement)
2. the common finger-prick (invasive) method of the TensorTip device (testing with three strip lots)
3. the pain-free (non-invasive) method
4. repeat the YSI reference method (endpoint measurement). 1, 2 and 4 will be performed by healthcare professionals, 3 will be performed by the patient. Thereafter, the study is finished and the patient can leave the study site.

What are the possible benefits and risks?
Benefits: the study is a technical testing of the device and does not provide any medical benefit for the patient. Therefore, the patient will receive a honorarium for study participation.

Risks: the risks involved are coming from the fingerpricking requirement for calibration and measurement, mainly pain when puncturing the fingertip, skin lesions and bleeding.

Where is the study run from?
Pfützner Science & Health Institute, Mainz, Germany.

When is the study starting and how long will it last?
July 2017 to September 2017.

Who is funding the study?
CNOGA Medical Ltd, the maker of the TensorTip device.

Who is the main contact?
Principal investigator: Prof. Andreas Pfützner, andreas.pfuetzner@pfuetzner-mainz.com

Contact information

Type(s)
Scientific

Contact name
Prof Andreas Pfützner

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CNG-NGM-002

Study information

Scientific Title
System accuracy of the invasive part of the Tensortip Combo glucometer (CoG) – clinical trial protocol in accordance with ISO15197:2015

Acronym
ISO Study

Study objectives
The invasive part of the TensorTip Combo Glucometer meets the acceptance criteria for system accuracy as set forth in ISO15197 (95% of paired values versus the YSI 2300 StatPlus reference method are within a range of +/-15 mg/dl for values below 100 mg/dl and +/-15% for values >=100 mg/dl)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission der Landesärztekammer Rheinland Pfalz (Ethics Committee of the Chamber of Physicians of the State of Rheinland-Pfalz), 20/07/2017, 00010932 DIMDI

Study design
Open-label prospective controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Accuracy of glucometer in determining blood glucose levels in patients with diabetes mellitus

Interventions
After enrollment and device calibration at home during the following week, patients will come to the study site for a single comparative blood glucose testing experiment. The patients check their glucose with a regular glucose meter and based on the result, the decision will be made to either start a comparative glucose test experiment right away or to allow glucose to be modified by means of food uptake or insulin injection, to meet certain patient numbers at different blood glucose levels. For the experiment, capillary blood will be taken by finger prick and tests for blood glucose will be made by means of either the YSI reference test, the invasive TensorTip CoG component , the non-invasive CoG device component, or another YSI reference test. After the final reference test, the patients will be discarded from the site, which concludes the trial.

Intervention Type
Device

Primary outcome measure

The bias between the results obtained with the invasive TensorTip CoG component from the mean reference results will be calculated and the data pairs will be analyzed by means of a consensus-error-grid analysis according to Parkes et al., 2000.

Secondary outcome measures
The bias between the results obtained with the non-invasive TensorTip CoG component from the mean reference results will be calculated and the data pairs will be analyzed by means of a consensus-error-grid analysis according to Parkes et al., 2000

Overall study start date
23/05/2017

Completion date
20/10/2017

Eligibility

Key inclusion criteria
Type 1 diabetes or type 2 diabetes or healthy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
36

Key exclusion criteria
1. Not able to perform study at the discretion of investigator
2. Uptake of high doses of vitamin C
3. Uptake of acetylsalicylic acid
4. Inability to operate device

Date of first enrolment
20/07/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment

Germany

Study participating centre
Pfützner Science & Health Institute
Mainz
Germany
55128

Sponsor information

Organisation
CNOGA Medical Ltd.

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Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
CNOGA Medical Ltd

Results and Publications

Publication and dissemination plan

Study results are going to be presented at several national (German) and international (American) diabetes conferences. In addition, the results will be included into the submission package for FDA approval of the device and a final manuscript will be prepared in 1Q2018.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent final study report provided to the IRB and regulatory agencies and the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018	06/11/2019	Yes	No