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Study to explore how accurately the CNOGA Combo glucose meter and the MTX meter measure blood sugar, blood pressure and other important body information when people are eating a meal

Submission date
27/03/2018

Recruitment status
No longer recruiting

Registration date
24/05/2018

Overall study status
Completed

Last Edited
23/04/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] 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 TensoTip ComboGlucometer (CoG) uses a painfree (non-invasive)method (by sending light with different wavelengths during a selected finger) to measure the sugar levels in the tissue of the finger. A second device, the MTX meter, uses the same technology to measure other body signals such as blood pressure, pulse, oxygen saturation, number of red blood cells, and others. In this study, the primary goal is to measure how close the CoG meter results are to commonly measured blood sugar values when the patient is eating a breakfast.

Who can participate?
People aged 18-80 years who are healthy or have type 1 or type 2 diabetes. People with HIV infection or hepatitis, people receiving dialysis, women who are breastfeeding or pregnant and people with scratches, scars, tattoos or skin conditions on the finger cannot take part.

What does the study involve?
Participants will eat breakfast at the trial centre. Measurements of blood sugar and other body signals will be taken at 30-minute intervals during the meal and for 3 hours after starting the meal using the CoG and MTX devices and other standard methods. For example, blood pressure will be tested with arm cuffs. After this meal experiment, the participants will be allowed to use the CoG device at home for blood sugar monitoring for 3 months. This gives them access to an unlimited number of pain-free blood sugar tests. Blood will be taken before and after the 3 months to investigate whether using a pain-free device at home can improve the overall well-being of the participants and their long-term blood sugar control.

What are the possible benefits and risks of participating?

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

When is the study starting and how long is it expected to run for?
July 2017 to August 2017.

Who is funding the study?
CNOGA Medical Ltd, an Israeli company that makes the CoG and MTX devices.

Who is the main contact?
Prof Dr Andreas Pfützner, Pfützner Science & Health Institute.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CNG-NGM-001

Study information

Scientific Title
Evaluation of the CNOGA Combo glucometer and the MTX non-invasive body signaling device during a standardized meal test in patients with diabetes mellitus and in healthy subjects in comparison with point-of-care reference methods for the respective parameters

Acronym
CNOGA MEAL STUDY

Study objectives
The purpose of this clinical study is to demonstrate the performance of both non-invasive CNOGA devices the TensorTip CoG measuring glucose and Hb A1c levels and the TensorTip MTX measuring different vascular biomarkers (blood pressure (systolic and diastolic) and SpO2, hemoglobin, peripheral pulse rate (PPR), pCO2, pO2, MAP, HCT, CO, pH, BV, peripheral pulse

wave (PPW), graphs of BP variation and additional hemodynamic parameters and graphs), when operated according to its instructions for use.

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), 12/07/2017, 00010925

Primary study design
Observational

Study design
Prospective single-center open-label uncontrolled 3-month study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Accuracy of devices in measuring health-related parameters in people with diabetes mellitus and healthy people

Interventions
The participants are trained to use the CNOGA Comboglycometer or the MTX Multimarker devices and will calibrate them for 1 week at home with multiple comparative measurements with an invasive blood sugar meter. Thereafter, they come to the trial site in the morning after an overnight fast and will eat a standardized breakfast and take their usual medication. Blood sugar will be measured 11 times before and after the meal uptake for a total of 3 h with several blood sugar meters and a reference method (YSI 2300 Stat Plus). Participants can then leave the site. The participants will then be allowed to use the devices at home for a total of 3 months. Additional visits will occur after 6 weeks (interim) and 12 weeks (final). At these visits blood will be drawn for measurement of glycemic control (HbA1c). At the final vist, the patients will also complete a standardized questionnaire regarding device use. This will conclude the study. Total study duration for one participant: 14 weeks

Intervention Type
Device

Primary outcome(s)
The primary outcome parameter is the mean observed difference between the non-invasive sugar measurements with the CNOGA ComboGlucometer and the reference method during the trial site visit.

Key secondary outcome(s)
1. Mean observed difference between the invasive blood sugar measurement with the CNOGA device and the reference method during the trial site visit
2. Comparison of long-term sugar control (HbA1c) at baseline and after 3 months
3. Other body signals (blood pressure, pulse, tissue oxygenation and others) will be measured with the non-invasive MTX device and compared to clinical reference methods during the meal experiment

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Type 1 diabetes mellitus or type 2 diabetes mellitus or healthy subjects
2. Aged 18-80 years

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Subjects requiring dialysis
2. Any conditions that may hamper good visual contact between the finger and sensor, such as raised birthmarks, scars, tattoos
3. Pregnancy
4. Nursing mothers
5. Any skin scratch(es) on the measured finger
6. Diagnosis of HIV infection or hepatitis

Date of first enrolment
15/07/2017

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
Germany

Study participating centre
Pfützner Science & Health Institute
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Sponsor information

Organisation
CNOGA Medical Ltd.

Funder(s)

Funder type
Not defined

Funder Name
CNOGA Medical Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Not expected to be made available