

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/04/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

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

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

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

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 visit, 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 measure

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.

Secondary outcome measures

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

Overall study start date

01/05/2017

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

15 patients with type 2 diabetes, 15 healthy subjects, 6 patients with type 1 diabetes

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

Haifa-Allee 20

mainz

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Sponsor information

Organisation

CNOGA Medical Ltd.

Sponsor details

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Sponsor type

Industry

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Funder(s)

Funder type

Not defined

Funder Name

CNOGA Medical Ltd

Results and Publications

Publication and dissemination plan

Results will be published at the ATTD conference in February 2018 in Vienna and at the German Diabetes Conference in May 2018 in Berlin. In addition two manuscripts (overall study results and subgroup analyses) have been submitted to J. Diabetes Sci. Technol. and Diabetes Technol. Ther., respectively.

Intention to publish date

01/03/2018

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