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Assessment of potential drug and substance interference on the performance of the CNOGA TensorTip blood glucose measuring device

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
13/05/2019

Overall study status
Completed

Last Edited
18/02/2020

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
After intake of drugs or supplements some commonly used glucometer show altered measurements results. This alteration is also called interference. Before a glucometer can enter into the market these interferences need to be characterized. This is normally evaluated in a laboratory study, where different concentration of drugs and supplements are added to venous blood samples and then the measurement capability is tested. The present glucometer has a non-invasive component and a laboratory study is not possible for the verification of possible interferences with drugs and supplement, because blood is not needed for these measurements. Therefore, the protocol of the present study was established. Here volunteers take in specific drugs and supplements in normal daily doses and then the non-invasive component of the glucometer is tested against reference method using capillary blood to evaluate possible interference substances.

Who can participate?
Healthy volunteers, without regular drug or supplement treatment with normal blood values evaluated in a safety parameter blood draw and without known sensitivities towards any of the tested drugs and supplements. Further volunteers with a history in alcoholism will be excluded as well.

What does the study involve?
The study involves 11 visits. During the first visit the safety parameter blood draw will be executed and the patients gets an introduction to the study glucometer. The study glucometer needs to be calibrated at least at 3 days with 8 measurements per day. In each of the following 10 remaining visits one drug or supplement (acetaminophen, ascorbic acid, diclofenac, ibuprofen, alcohol, coffein, acetylic acid, xylose, mannose, omega-3 fatty acid) will be tested for interferences with the study glucometer. During each visit, the blood glucose will be evaluated at 6 different time points. The time points are dependent on the uptake of the drug or supplement to the body, so the visit take between 1,5h and 8h.

What are the possible benefits and risks of participating?
There is no personal benefit. But there is a potential benefit for all diabetic persons. Participants will be remunerated for their time.

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

When is the study starting and how long is it expected to run for?
November 2018 for 2 weeks

Who is funding the study?
CNOGA Ltd.

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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CNG-NGM-004

Study information

Scientific Title
Clinical assessment of potential drug and substance interference on the performance of the CNOGA TensorTip COMBO GLUCOMETER (CoG)

Acronym

CNG-NGM-004

Study objectives
To investigate the potential interference of frequently used drugs and nutritional supplements on the performance of the CoG device

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2018, Landesärztekammer Rheinland-Pfalz; states medical association Rhineland (Deutschhauspl. 3, 55116 Mainz, Germany; +49 6131 288220; kammer@laek-rlp.de) ref: 2018-13243-MPG, Eudamed-Nr. CIV-18-05-023925

Study design
Open label prospective comparative single-center

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
diabetes

Interventions
All participants will get an introduction to the TENSORTIP COG (MP) and one device will be individually assigned. This is followed by a week of calibration by the participants at home. All calibration measurement results will be manually and electronically recorded.
All following visits testing the interferents (approved common drugs and supplements) will start with a measurement of blood glucose with the comparator method, followed by invasive and non-invasive measurements with the COG device. To ensure constantly stable blood glucose values, after the measurement with the COG device, again capillary blood for a measurement with the comparator device will be taken. After the initial measurement the respective amount of one of the interferents will be taken and the measurement as described before will be repeated at Tmax and Thalfmax of the respective interferent and additional three time points in order to capture the pharmacokinetic curve of the relevant interferent. The following interferents will be tested in ten consecutive visits with an interval of one week each: Acetaminophen, Ascorbic Acid, Diclofenac, Ibuprofen, Ethyl Alcohol, Caffeine, Acetyl Salicylic Acid, Xylose, Mannose, 3-Omega-Fatty Acids.
The actual substance concentration at each of the six measuring time points per visit/substance will be evaluated in an external lab.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)

Influence of different drugs and/or nutritional supplements on the result of the non-invasive glucose measuring CoG device measured weekly over 10-weeks.

Key secondary outcome(s))
1. Impact of different drugs and/or nutritional supplements on the results of the invasive CoG device in comparison to the YSI reference method
2. Impact of different drugs and/or nutritional supplements on the results of the YSI device in comparison to a standard laboratory method.

Completion date
25/02/2019

Eligibility

Key inclusion criteria
1. Healthy subjects verified by safety chemistry and blood count
2. Able to complete and understand informed consent form (by him/herself or by his/her guardian)
3. 18 years old and above
4. No constant treatment with medication
5. Safety biochemistry and blood count with exclusively values in normal range

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Severe life-threatening disease
2. Anatomical conditions that may hamper good contact between the device and the measured finger, at the discretion of the investigator
3. Pregnancy
4. Nursing mothers
5. Healthy volunteers with a hypersensitivity to any of the tested interferents
6. History of alcoholism (anamnestic exclusion)

Date of first enrolment

01/11/2018

Date of final enrolment
16/11/2018

Locations

Countries of recruitment
Germany

Study participating centre
Pfützner Science & Health Institute
Haifa-Allee 8
D-55128 Mainz, Germany
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Sponsor information

Organisation
CNOGA Ltd.

Funder(s)

Funder type
Industry

Funder Name
CNOGA Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/07/2019	18/02/2020	No	No