Carotid body dysfunction in type 2 diabetes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON50001

Source
ToetsingOnline

Brief title
Carotid body function in T2DM

Condition

- Diabetic complications

Synonym
Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Demcom

Intervention

Keyword: Carotid body, Hypoxia, Insulin, Ventilation

Outcome measures

Primary outcome

Hypoxic ventilatory response

Secondary outcome

Heart rate variability

Study description

Background summary

The glomus body (or carotid body, CB) is the main oxygen sensor in the blood. In the event that the oxygen concentration in the blood decreases, this leads to a hyperventilation reaction, which restores oxygen uptake. A drop in oxygen concentration can occur during sleep, at high altitude, while flying in modern airplanes, and also in the case of lung and heart disease. The functionality of the CB is also important in diabetes mellitus because the CB also measures the glucose concentration in the blood. Elevated levels of insulin in the blood in particular can have an effect on the CBs. We want to study whether this also influences breathing.

Study objective

The aim of this research is twofold:
1) Determining the functionality of the oxygen sensor in the neck (the glomus body or *carotid body* during the administration of glucose and insulin, a so-called euglycemic hyperinsular clamp.
2) Validating a new oxygen sensor on the skin. This sensor is glued to the skin. This part of the research is being carried out in part by Demcom, a Dutch engineering company.

Study design

Observational non randomized study

Study burden and risks

We estimate the burden as minor with the main side effect being headache (can be treated well with paracetamol).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years and older
Non insulin dependent DM
No medical disease
Vital signs within specific boundries
Healthy apart from their DM
\See page 13 of the protocol

Exclusion criteria

* Insulin dependent diabetes mellitus
* Diagnosed Obstructive Sleep Apnea (OSAS) or high suspicion of OSAS determined by a STOP-BANG score > 5
* Respiratory or cardiovascular disease
* Smoking/vaping
* Positive pregnancy test
* conditions that result in elevated levels of methaemoglobinia
* body mass index > 35 kg/m2
* Use of illicit drugs
* Use of prescription opioids or benzodiazepines
* Failure of the drug of abuse tests at screening or check-in.
* History of dyspnea, asthma, tuberculosis, chronic obstructive pulmonary disease, or any other ventilatory / lung disease.
* Subjects with excessive facial hair preventing sealing of the occlusive face mask.
* Subjects who, in the opinion of the investigator, will not be able to participate optimally in the study.
* Subject who has a history of any infectious disease within 4 weeks prior to drug administration that in the opinion of the investigator, affects the subject*s ability to participate in the trial.
* Subjects who are part of the study staff personnel or family members of the study staff personnel.
* Subjects who have demonstrated allergic reactions (e.g., food, drug, atopic reactions or asthmatic episodes) which, in the opinion of the investigator and sponsor, interfere with their ability to participate in the trial.
* Personal or family history of arrhythmias or ECG conductance abnormalities.
* Hypokalemia defined as <3.5 mmol/L

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	SQ1 draagbare sensor
Registration:	No

Ethics review

Approved WMO

Date:	08-10-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78476.000.21

Study results

Date completed:	12-08-2022
Actual enrolment:	32