Carotid body dysfunction in type 2 diabetes

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Type 2 diabetes have altered chemosensitivity and are in fact sympathetically overactive compared to healthy controls during a hyperinsulinemic euglycemic clamp.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21994

Bron
Nationaal Trial Register

Verkorte titel
CBHYPOXIA

Aandoening

Diabetes Mellitus

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: Smartqare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the change in the slope of the hypoxic ventilatory response curve from baseline to euglycemic hyperinsulinemia in patients with type 2 diabetes compared to healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

During the COVID-19 pandemic patients with comorbidities such as hypertension, diabetes mellitus, obesity and pregnancy were overrepresented in the population that was admitted to the hospital. Morbidity and mortality due to SARS-COV-2 infection was higher in these patients compared to patients without these comorbidities. The higher incidence, morbidity and mortality is suggestive of an underlying mechanism that puts these patients more at risk. A proposed mechanism is the sympathetic overactivity that is associated with these conditions. Recently, it has become clear that the carotid bodies play an important role in sympathetic overactivity in these conditions. Dysfunction of this organ is associated with decreased chemosensitivity, disruption of insulin sensitivity, but is also associated with changes in neurohumoral control in response to infection. Whether carotid body dysfunction can explain the severity of SARS-COV-2 infection remains to be seen. The aim of this study is to find whether patients with type 2 diabetes have altered chemosensitivity and are in fact sympathetically overactive compared to healthy controls and during a hyperinsulinemic euglycemic clamp. Findings could help explain why type 2 diabetes patients are more heavily affected by SARS-COV-2 and could identify potential targets for treatment in these patients.

Doel van het onderzoek

Type 2 diabetes have altered chemosensitivity and are in fact sympathetically overactive compared to healthy controls during a hyperinsulinemic euglycemic clamp.

Onderzoeksopzet

Screening, one visit

Onderzoeksproduct en/of interventie

Euglycemic hyperinsulinemic clamp; hypoxic ventilalatory response

Contactpersonen

Publiek

LUMC
Rutger van der Schrier

071-5299893

Wetenschappelijk

LUMC
Rutger van der Schrier

071-5299893

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 18 years and older
• Subjects must be willing to give written informed consent for the trial and able to adhere to dose and visit schedule.
• Non-insulin-dependent diabetes mellitus (NIDDM) or healthy sex, age (± 3 yrs) and BMI (± 3 kg/m2) matched controls.
• Have no clinical or electrocardiographic signs of ischemic heart disease as determined by the Investigator with normal cardiac intervals appropriate for their gender. The Screening 12 lead ECG conduction intervals must be within gender specific normal range (e.g., QTcF ≤ 430 msec, PR interval ≤ 220 msec). ECGs are to be judged by the investigator or sub investigator as per standardized procedures.
• Vital sign measurements must be within the following ranges: (Individuals with values outside (or indicate lower or higher) of these ranges may be enrolled if clinically acceptable to the investigator and sponsor.
o body temperature, between 35.5°C and 37.5°C
o systolic blood pressure, 90 to 150 mmHg
o diastolic blood pressure, 40 to 95 mmHg
o pulse rate, 40 to 100 bpm
• Subjects must be free of any clinically significant disease that would interfere with the study evaluations.
• Subjects presenting out of range values of lab/ECG/vital signs compatible with normal variation of the normal healthy subject can be included in the study at the investigator’s discretion and sponsor written approval.
• Positive Allen’s test
• Fitzpatrick skin type I or II

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2021
Aantal proefpersonen:	30

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
yet to be determined

Ethische beoordeling

Positief advies

Datum:	05-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9769
Ander register	METC Leiden-Den Haag-Delft. (METC-LDD) : P21-082

Resultaten

Samenvatting resultaten
n/a