The impact of passive heat treatment on glycaemic response during an oral glucose tolerance test in diabetic patients

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To assess the acute impact of passive heat treatment on the post-prandial glycaemic response during an OGTT in T2DM patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51495

Source
ToetsingOnline

Brief title
Sauna OGTT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes mellitus type 2, Insulin sensitivity, Passive heat treatment, Sauna

Outcome measures

Primary outcome

To assess the acute impact of PHT by means of infrared sauna bathing on glycaemic response as defined by the Matsuda Index in an oral glucose tolerance test (OGTT) in T2DM patients.

Secondary outcome

Determine plasma volume, body mass, skin and core body temperature, blood pressure and heart rate before and after passive heat treatment.

Study description

Background summary

Type 2 diabetes mellitus (T2DM) is a metabolic disease with a rapidly increasing incidence world-wide. The disease is characterized by a decreased glucose tolerance as a result of insulin resistance, resulting in poor blood glycaemic control. Blood glucose lowering medications are widely available, but their effect stagnates as T2DM progresses. New treatment regimens are required to combat the disease. Although therapies such as physical exercise have been shown to induce beneficial effects on glycaemic control in T2DM patients, not all patients are able to perform exercise. Passive heating treatment (PHT) might be an alternative strategy to reduce insulin resistance, as it has been postulated to have comparable effects on the cardiovascular system as exercise. PHT has been linked to numerous health benefits, including improved cardiovascular- and pulmonary function, pain alleviation and metabolic health. In addition, long term use of PHT shows promising effects on glycaemic control in T2DM patients. However, the acute effects of PHT on glucoregulation are yet to be determined.

Study objective

To assess the acute impact of passive heat treatment on the post-prandial

glycaemic response during an OGTT in T2DM patients.

Study design

Crossover, randomized, controlled trial

Intervention

Participants will be subjected to two infrared sauna bathing (heated and non-heated) sessions. Glycaemic control will be assessed during following both sessions by performing an OGTT. Body mass, body temperature, blood pressure, and heart rate will be monitored during the sessions. Blood samples will be collected throughout the sessions to assess glucose and insulin concentrations, and plasma volume.

Study burden and risks

The risks associated with participation are minimal. The burden can be considered as low, considering the time investment of the participants and test day procedures involved. Participants will visit the University for one screening and two test days (1 week interval). The first visit will involve a screening visit (~2 h), during which the eligibility of the participant will be assessed. During the screening visit, a medical questionnaire is filled out and a bioelectrical impedance (BIA) scan will be performed to assess body composition, which does not cause any discomfort for the participant.
Participants will not be allowed to eat, drink (except water in small amounts), perform strenuous exercise for 8 hours prior to the screening session.
Participants will participate in two *PHT test days* of ~4-5h. Insertion of the catheters during test days is comparable to a normal blood draw and the only risk is a small local hematoma. During each experimental test day, 8 blood samples (~80mL/day) will be obtained. The total amount of blood collected during this study (~160 mL) is far less than the amount of a blood donation (500 mL) and will be completely restored in less than 1 month.
For each *PHT test day* visit participants are required to come to the university in a fasted state, not having consumed any food or beverages (except for water) as from 22:00 the evening before. Participants are required to eat a standardized meal the evenings preceding each test days. Also, 2 days prior to the experimental test days participants need to record their food intake and activities performed. During these 2 days participants are not allowed to perform heavy physical exercise or drink alcohol.
A commercially available infrared sauna will be used for the PHT-intervention. Participants will perform 2 PHT session (heated and non-heated). Each session will last 40 minutes. For diabetic older adults, there is a minor risk of being exposed to this PHT-protocol. Dehydration and excessive sweating might influence blood pressure and could cause hyper- or hypoglycemia. To monitor this risk, finger prick equipment will be available to assess glucose levels in

case a participant indicates not feeling well. In addition, blood pressure measurement will be performed. Subjects will be provided with a rehydration protocol to replace the fluid that was lost during the PHT session after the OGTT. PHT is known to be associated with many different health benefits including improved blood pressure, metabolic profile, relaxation, reduced pain sensation and reduced cardiovascular risk.
Core body will be monitored using an ear thermometer. This is safe, non-invasive and easy to use. Skin temperature will be measured using iButton, a peripheral thermometry device applied on the skin, which is also non-invasive and safe to use.

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

>50 years old
BMI 18.5-35 kg/m2
Diabetes mellitus type 2
Use of oral glucose lowering medication
Able to provide written informed consent

Exclusion criteria

Insulin dependence
Changes in diabetes medication in the past 3 months
Allergy for one of the food items used
>5% weight change in the previous 6 months
Participating in a structured (progressive) exercise program, or in the past 3 months.
Frequent (once per week or more) user of infrared (or traditional) sauna in the past 3 months
Inability to tolerate sauna/high temperatures
Smoking
Diagnosed with cardiovascular disease (e.g. unstable angina pectoris or recent myocardial infarction), kidney failure (eGFR < 60 ml/min/1.73m2), rheumatoid arthritis
Diagnosed musculoskeletal, GI tract, metabolic (except diabetes) or pulmonary (e.g. COPD) disorders that are expected to influence study outcomes
Having a pacemaker, defibrillator, or any other type of metal implant

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2023
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL82416.068.22
Other	Nog te registeren