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Does ethnicity affect blood pressure regulation?

Submission date 08/11/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/12/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/12/2018	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiovascular diseases are still one of the worldwide leading causes for hospitalisation and death, with an immense effect on healthcare and social budgets. This has led leading authorities and institutions to increase their effort concerning primary prevention and personalized medicine. In this context, a very popular primary prevention strategy comes with reducing the intake of sugar-sweetened beverages because of their impact on cardiovascular and metabolic health. Recently, our group has shown that that blood pressure – a major contributor for cardiovascular diseases – responses to glucose were different between Caucasian and South Asian individuals.
We aim to investigate blood pressure regulation in subjects from South Asian and Caucasian ancestry and hypothesize that subjects from South Asia (India, Pakistan, Bangladesh, Sri Lanka or Nepal) exhibit an increased blood pressure response to an oral glucose drink when compared to matched group of Caucasian individuals.

Who can participate?
Healthy adult males aged 20-31 who are either Caucasian or South Asian (South Asian individuals must originate from India, Pakistan, Bangladesh, Sri Lanka or Nepal)

What does the study involve?
All study participants will undergo the same treatment, where they drink a sugary solution comprised of 75 g of glucose dissolved in 300 mL of tap water within 4 minutes. Subsequently, the blood pressure responses to this test will be measured and compared between people from South Asian and Caucasian ancestry.

What are the possible benefits and risks of participating?
There is no benefit in participating in this study with the exception of a comprehensive cardiovascular investigation, which could reveal certain conditions such as elevation of blood pressure levels, impaired glucose metabolism or type 2 diabetes.
The blood sampling process (i.e. cannulation and manipulation on the catheter to withdraw the blood sample) may result in a very slight pain, as well as removal of the electrodes. Moreover, it is possible that bruises emerge on the spot where blood is collected.

Where is the study run from?
Department of Endocrinology, Metabolism and Cardiovascular System at the Faculty of Science and Medicine at the University of Fribourg, Switzerland

When is the study starting and how long is it expected to run for?
June 2018 to December 2019

Who is funding the study?
Faculty of Science and Medicine, University of Fribourg (Switzerland)

Who is the main contact?
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Study website
N/A

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cardiovascular and metabolic responses to glucose in South Asians and Caucasians: the impact of ethnicity on blood pressure regulation

Study objectives
Blood pressure dysregulation (increasing blood pressure parameters in response to a standardized glucose drink) will occur more frequently in people from South Asian ancestry compared to people from Caucasian ancestry.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission cantonale (Vaud, Switzerland) d'éthique de la recherché sur l'être humain (CER-VD), 06/08/2015, 239/1
Study amendment approval by Commission cantonale (Vaud, Switzerland) d'éthique de la recherché sur l'être humain (CER-VD), on 05/10/2018, PB_2018-00178 (239/15)

Study design
Interventional prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Blood pressure regulation

Interventions
Participants enter the study in a randomised fashion after an initial recruitment process. The order of the subject's test entry before the very first test will be randomised by using a random sequence generator where the test entry order will be determined for each subject.
All participants will complete an oral glucose tolerance test (OGTT) using a glucose drink containing 75 g of glucose dissolved in 300 ml water. This will be ingested over a 4 minute period. Changes in blood glucose levels will be monitored before the OGTT and 120 minutes following this. A normal OGTT will be classed as a 2 hour blood glucose value less than 140 mg /dL (less than 7.8 mmol/L). An impaired OGTT will be classed as a 2 hour glucose value between 140 and 199 mg/dL (7.8–11.1 mmol/L). Every test with an impaired OGTT will not enter further analysis.

Intervention Type
Other

Primary outcome measure
1. The following haemodynamic parameters will be assessed continuously, starting with a 30 minute baseline and continued after the oral glucose tolerance test (OGTT) for another 120 minutes using a Task Force Monitor:
1.1. Blood pressure (systolic and diastolic)
1.2. Heart rate
1.3. Stroke volume
1.4. Heather index (marker for myocardial contractility)
2. The following blood parameters will be assessed at the end of the 30 minute baseline and after the OGTT every 30 minutes until the end of the OGTT (120 minutes post-drink):
2.1. Plasma glucose, assessed using hexokinase Glucose HK Gen 3
2.2. Plasma insulin, assessed using ELISA

Secondary outcome measures
1. The following haemodynamic parameters will be assessed continuouslty during the 30 minute baseline and over the 120 minutes following the OGTT:
1.1. Cardiac output, assessed using impedance cardiography
1.2. Total peripheral resistance, assessed by dividing mean blood pressure by cardiac output
1.3. Index of contractility, assessed using impedance cardiography
1.4. Thoracic fluid contact, assessed using impedance cardiography
1.5. Thoracic impedance, assessed using impedance cardiography
1.6. Spectral analysis parameters, assessed using power spectral analysis
1.7. Baroreflex sensitivity, assessed using the sequence technique
2. Central arterial waveform analysis of the following parameters, performed using applanation tonometry prior to each blood sample:
2.1. Central systolic blood pressure
2.2. Central diastolic blood pressure
2.3. Mean blood pressure
2.4. Augmentation index (AIx75)
2.5. Ejection duration index
2.6. Sub-endocardial viability ratio
3. The following anthropometric parameters, assessed using a calibrated scale and a statiometer prior to the OGTT:
3.1. Weight
3.2. Height
3.3. Sitting heigh
3.4. Leg length
3.5. Waist circumference
3.6. Hip circumference
4. The following body composition parameters, assessed using body impedance measurements and the deuterium dilution technique prior to the OGTT:
4.1. Total body fat in kg and %
4.2. Trunk (abdominal) fat in %
4.3. Fat free mass in kg and %
4.4. Skeletal muscle mass in kg and %

Overall study start date
01/06/2018

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Healthy
2. Non-smoking
3. EITHER of South Asian ancestry (India, Pakistan, Bangladesh, Sri Lanka or Nepal) OR Caucasian
4. BMI between 18.5 and 24.9 kg/m²
5. Aged 20-30 years
6. Male

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
24

Key exclusion criteria
1. Diagnosed as diabetics based on the following criteria:
1.1. Fasting glucose levels equal to or exceeds 126 mg/dL (7.0 mmol/L)
1.2. 2 HOUR glucose equal to or exceeds 200 mg/dL (11.1 mmol/L)
2. Any medical condition which could interfere with the measured variables, including cardiovascular, gastrointestinal, neurological or overt metabolic disorders
3. Currently using medication for acute or chronic illness
4. Competition athletes
5. Overtly sedentary
6. Eating disorders
7. Fear or have adverse reactions to cannulation

Date of first enrolment
01/01/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Faculty of Science and Medicine. Department of Endocrinology, Metabolism and Cardiovascular System. University of Fribourg
Chemin du Musée 5
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1700

Sponsor information

Organisation
University of Fribourg - Faculty of Science and Medicine

Sponsor details
Chemin du Musée 8
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Sponsor type
University/education

ROR
https://ror.org/022fs9h90

Funder(s)

Funder type
University/education

Funder Name
Intramural funding from the budget provided by the Faculty of Science and Medicine, University of Fribourg

Results and Publications

Publication and dissemination plan
Primary and secondary outcome results are intended to be published together, or separately, and be submitted to a well-respected peer-review journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as we will not have consent from our participants to share any of their data and therefore we are legally not allowed to disseminate the subject's data.

IPD sharing plan summary

Not expected to be made available