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Does a ketone drink improve cardiac energetics?

Submission date
18/06/2018

Recruitment status
No longer recruiting

Registration date
20/06/2018

Overall study status
Completed

Last Edited
19/06/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes patients have impaired energy metabolism in the heart (cardiac energetics). This can be measured as low PCr/ATP. Heart and blood vessel (cardiovascular) disease is the most common cause of death in people living with type 2 diabetes, and there is no specific treatment for cardiovascular complications in diabetes.
Ketones can improve energy metabolism in the heart. TdeltaS Ltd has developed a ketone ester drink named DeltaG® which quickly and safely elevates ketone blood levels. It is already proven to be safe as a drink in healthy humans.
The aim of this trial is to investigate whether drinking a ketone solution can increase PCr/ATP levels in the hearts of healthy volunteers. The results will guide future studies in people with diabetes or heart failure.

Who can participate?
Healthy volunteers aged 18-70 years

What does the study involve?
The participants must fast (eat no food) for 24 hours. Drinking water is allowed and encouraged during the fast. They will then undergo an MRI scan before drinking a mix of 25 ml of a ketone monoester and water. They will have another MRI scan 30 minutes after drinking the ketone solution.

What are the possible benefits and risks of participating?
The ketone drink has a very bitter taste. It is safe to drink, but may cause mild headaches and abdominal cramps. The MRI scan is not painful and doesn't use radiation, however some people experience claustrophobia while being in the scanner. There are no expected benefits of taking part.

Where is the study run from?
The Oxford Centre for Functional MRI of the Brain (UK)

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

Who is funding the study?
TdeltaS Ltd.

Who is the main contact?
Dr Adrian Soto.
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DG7T

Study information

Scientific Title
The acute effect of a ketone monoester on cardiac PCr/ATP

Study objectives
Ketone ingestion will lower cardiac phosphocreatine (PCr)/ATP ratio.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval will be sought following trial registration.

Study design

Prospective open-label basic science study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
After consent, we will ask participants to fast for 24 hours. During this period, drinking water is allowed and encouraged. Afterwards, we will measure baseline blood ketone levels and perform a Phosphorus Magnetic Resonance Spectroscopy scan (31P MRS) which lasts around 30 minutes. Then, we will ask participants to drink a mix of 25 ml of a ketone monoester and water and repeat the 31P MRS scan and the blood ketone levels measurement. In total, participant involvement lasts around 26 hours.

Intervention Type
Supplement

Primary outcome measure
Cardiac phosphocreatine/ATP (PCr/ATP) ratio assessed using 31P MRS scan after 24 h fasting and 30 minutes after drinking the ketone monester solution

Secondary outcome measures
None

Overall study start date
01/04/2018

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. Fluent in English with no communication impairments
2. Willing and able to give informed consent for participation in the study

3. Aged 18-70 years (inclusive)
4. No known medical diagnosis
5. No prescribed medication
6. In the Investigator's opinion, able and willing to comply with all study requirements

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Contraindication for undergoing Magnetic Resonance Imaging (MRI), such as metallic implanted devices, shrapnel or claustrophobia
2. Pregnant, lactating or planning to get pregnant
3. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the experiment, or the participant's ability to participate in the study.

Date of first enrolment
01/08/2018

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Centre for Functional MRI of the Brain
United Kingdom
OX3 9DU

Sponsor information

Organisation
TdeltaS Ltd

Sponsor details
30 Upper High Street
Thame, Oxfordshire
United Kingdom
OX9 3EZ

Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
TdeltaS Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date