

Does a ketone drink improve cardiac energetics?

Submission date 18/06/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 20/06/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/06/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

None

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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

United Kingdom

England

Study participating centre

Oxford Centre for Functional MRI of the Brain

United Kingdom

OX3 9DU

Sponsor information

Organisation

TdeltaS Ltd

Funder(s)

Funder type

Not defined

Funder Name

Results and Publications

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