Cardiac metabolic profiling in the fed state

Published: 09-06-2022
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The primary aim of this study is to provide insight into cardiac substrate utilization in the fed state.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON56735

Source
ToetsingOnline

Brief title
CAMP

Condition

- Heart failures

Synonym
Cardiac nutrition / cardiac substrate metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac, metabolism, PVI

Outcome measures

Primary outcome

Cardiac arteriovenous (A-V) gradient of metabolites, reflecting uptake and

release of metabolites in the heart in the fed state.

Secondary outcome

To be determined metabolites

Study description

Background summary

The heart requires tremendous amounts of energy to sustain its mechanical work. The heart can utilize various metabolic substrates to generate energy, including carbohydrates, lipids, amino acids and ketone bodies. However, most research into the cardiac fuel usage has been done in rodents and surprisingly little is known about the cardiac fuel use in patients with heart disease. A recent study in patients with heart disease showed that the heart mainly uses fatty acids as a fuel source and only minute amounts of glucose. This study was, however, performed in fasting subjects; which could have an important effect on substrate preference.

Study objective

The primary aim of this study is to provide insight into cardiac substrate utilization in the fed state.

Study design

Monocenter non-randomized intervention study.

Intervention

Administration of peripheral parenteral nutrition (PPN) via a peripheral line. Determination of metabolites will be done via arteriovenous sampling from the already placed catheters.

Study burden and risks

Patients will participate during an elective PVI procedure which would have taken place regardless of the current study. During this study they will receive peripheral parenteral nutrition PPN) through an intravenous (iv) line that is already in place for the procedure. In some cases the anesthesiologist may choose for practical reasons to place an extra iv line, however, this is not necessary for participation in this study. Per patient this will lead to a maximum volume load of 750 ml. Patients will not have to pay an extra visit to the hospital for the purpose of this study and this study will not prolong the total procedure time. Subjects do not have direct benefits from participating in this study.

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

Adult (>18 years old) undergoing elective pulmonary vein isolation (PVI)
Give verbral and written informed consent

Exclusion criteria

Chronic renal disease with an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m2
Chronic liver disease and/or severe liver dysfunction with ASAT and/or ALAT > 3x the upper limit of normal (ULN)
Pregnancy or breastfeeding
Insulin dependent diabetics
Congenital metabolic disease
Weight below 40 kg
Inability to understand and read Dutch or English
Known allergy or hypersensitivity to any of the non-investigational products in the study protocol
Any other clinical condition that would jeopardize patients safety while participating in this trial, or may prevent the patient from adhering to the trial protocol.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-08-2022
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL77502.042.21