Biomarkers in mitochondrial patients and healthy volunteers

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON21411

Source
Nationaal Trial Register

Brief title
CHDR2111

Health condition

cardiomyopathy, mitochondrial diseases, energy metabolism disease

Sponsors and support

Primary sponsor: OMEICOS Therapeutics GmbH
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

The difference in performance of mitochondrial function assays between MitoD subjects and HV subjects

Secondary outcome

Difference in blood serum/plasma markers associated with inflammation and oxidative stress (IL-6, hs-CRP, PTX-3, and GDF-15) between MitoD subjects and HV subjects

Study description

Background summary

OMT-28 is a fully synthetic small molecule that belongs to the family of 17, 18-epoxyeicosatetraenoic acid (17,18-EEQ) analogs, a natural metabolite of the omega-3 fatty acid eicosapentaenoic acid (EPA). The safety of various doses of OMT-28 was studied in toxicology studies in various species, as well as in a First-in-Human study including a Single-Ascending-Dose (SAD) and Multiple Ascending-Dose (MAD) part, and a Phase 2a Proof-of-Concept (PoC) study (PROMISE-AF) in subjects with atrial fibrillation. 3 Recent non-clinical studies showed the potential of OMT-28 to positively affect mitochondrial function and survival. Therefore, OMT-28 is currently being developed for the treatment of cardiomyopathy in subjects with mitochondrial diseases and in subjects with coronary artery disease.
Subjects with mitochondrial disorder and cardiomyopathy might benefit from treatment with OMT-28, due to the potential positive effects
of OMT-28 on mitochondrial function and survival. This non-interventional study aims to characterize these subjects using different markers of mitochondrial function and inflammation, and to assess using ex-vivo assays in blood the potential effect of OMT-28 on mitochondrial function.
The aim of this non-interventional study is to characterize subjects regarding their levels of mitochondrial dysfunction and inflammation
markers, and to identify those subjects who might benefit most from OMT-28 treatment based on the ex-vivo blood assay results. The
results of this study are supposed to guide the design of future clinical interventional studies with OMT-28.

Study objective

To explore, whether markers of mitochondrial dysfunction measured in isolated PBMCs or immune cell subpopulations differ between subjects with mitochondrial disorders and cardiomyopathy and healthy volunteers.

Study design

Screening and blood donation will occur on the same day. No treatment period and follow up.

Intervention

N.A.

Contacts

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Eligibility criteria

Inclusion criteria

All subjects
1. Adults between 18 and 75 years, inclusive at screening
2. Body mass index (BMI) 18.0 to 30.0 kg/m2, inclusive at screening
3. Ability and willingness to abstain from alcohol at study visit
4. Subject (and/or parent/legal guardian) has voluntarily signed consent form.
5. Willingness and ability to comply with all study procedures.
6. Ability to communicate with the investigator in Dutch or English

Subjects of cohort 1 with Mitochondrial Disorder (in addition)
7. Diagnosis of Mitochondrial Disorder, confirmed by:
a. Genetic testing at any time prior to screening showing m.3243A>G mutation
b. Newcastle Mitochondrial Disease Scale (NMDAS) score ≥11
8. Current cardiomyopathy documented as:
Left ventricular hypertrophy (LVH) on echocardiography (defined as interventricular septal thickness (IVS) / left
ventricular posterior wall thickness (LVPW)) ≥ 11mm or LV mass indexed ≥ 115 g/m2

Subjects of cohort 2 Healthy Volunteers (in addition)
9. Judged to be in good health in the opinion of the Investigator on the basis of a medical evaluation that reveals
the absence of any clinically relevant abnormality
10. Matching to MitoD group for age (+/- 5 years), gender, and BMI (+/- 3 kg/m2).

Exclusion criteria

2. Women with positive urine hCG test at screening
3. Subject has a hemoglobin values outside the normal limits (as per local lab)
4. Subject has received drug therapy with any cytostatic, sGC stimulator/activator or nitrate agent during the last 3 months
5. Subjects with evidence of arterial hypertension
6. Subjects with severe aortic valve stenosis
7. Subject has received drug therapy with Metformin during last 3 months
8. Significant psychiatric or neurological disorder that would inhibit the subject from being compliant with study procedures
14. Positive nasopharyngeal rapid antigen test for SARS-CoV-2 at admission to the clinical research center
15. Subject has received any vaccination in the last 2 weeks prior to Visit 1
Subjects of cohort 2 Healthy Volunteers (in addition)
16. Subject has acute decompensated hepatic, gastrointestinal, respiratory, cardiovascular, metabolic, immunological, or hormonal disorders.

Study design

Design

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-07-2021
Enrollment:	16
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	26-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51060
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9830
CCMO	NL77982.056.21
OMON	NL-OMON51060

Study results

Summary results
N.A.