Insulin sensitivity in adults with a mitochondrial disorder.

Published: 10-11-2009
Last updated: 04-05-2024

The aim of the study is to investigate insulin sensitivity in patients with an inborn mitochondrial disorder due to a defect in the oxidative phosphorylation (OXPHOS).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON32965

Source
ToetsingOnline

Brief title
Insulin sensitivity in adults with mitochondrial disorder.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Inborn errors of metabolism

Synonym
diabetes mellitus and mitochondrial disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: FBW

Intervention

Keyword: diabetes mellitus, euglycaemic clamp study, Insulin sensitivity, mitochondrial

Outcome measures

Primary outcome

The insulin sensitivity index (Mi-value) is used to kwantify insulin

sensitivity. A difference of more than 30% between the patients and the control

group is considered clinically relevant.

Secondary outcome

not applicable

Study description

Background summary

Mitochondrial dysfunction is associated with insulin resistance and diabetes mellitus type 2. If patients with an inborn mitochondrial disorder are at risk for developing insulin resistance is unknown.

Study objective

The aim of the study is to investigate insulin sensitivity in patients with an inborn mitochondrial disorder due to a defect in the oxidative phosphorylation (OXPHOS).

Study design

a case-control study.

Study burden and risks

The duration of the study is 4-5 hours. The patient needs to be sober before the start of the study. The protocol includes a short questionnaire. Then, two intravenous accesses are needed for the clamp study for frequent blood analysis and administration of insulin and glucose. In theory, hypoglycemia can occur. This risk is minimized since glucose levels are checked very frequently.

Because lactate levels can increase during the clamp study, these levels are monitored.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients with an inborn mitochondrial disorder due to a defect in the oxidative phosphorylation (OXPHOS).

Exclusion criteria

diabetes mellitus, mental retardation or the use of drugs that influence glucose metabolism.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2010
Enrollment:	14
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	10-11-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL29209.091.09