Assessment of the critical unit (microcirculation and mitochondrial function) in pre-operative screening.

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To ascertain differences in mitochondrial and microcirculatory parameters between healthy older adults (> 65 years and ASA1-2) and more vulnerable elderly patients (> 65 years and ASA 3-4).

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56822

Source
ToetsingOnline

Brief title
Assessment of the Critical Unit

Condition

- Other condition

Synonym
mitochondrial dysfunction, reduced metabolic capacity

Health condition

ouderdom en kwetsbaarheid

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COMET, microcirculation, mitochondrial oxygenation, preoperative

Outcome measures

Primary outcome

Primary parameters are mitochondrial oxygen tension (mitoPO2), mitochondrial oxygen consumption (mitoVO2) and microcirculatory perfusion, with the latter encompassing total and perfused vessel density, proportion of perfused vessels, microvascular flow index, and vessel diameters

Secondary outcome

- MitoPO2 (mmHg).

- MitoPO2 after extercise (1MSTS test)

- metabolic frailty according the fried frailty phenotype assessment

- Mitochondrial function in platelets.

- Mitochondrial DNA in plasma as a marker of mitochondrial damage

- Mitochondrial function in peripheral blood mononuclear cells

- Post-operative complications

- Length of hospital stay

- Readiness for hospital discharge (using the RN-RHDS and the PT-RHDS) (30)

- Postoperative factors: patient outcome (according to Clavien-Dindo complica-tion classification). (31)

Study description

Background summary

Rationale: The study aims to address the growing need for improved perioperative care in frail elderly patients, acknowledging the challenges posed by their reduced metabolic capacity and increased risk of postoperative complications. In particular, this study is the first step in our goal to improve preoperative screening, and subsequent patient management, by incorporating mitochondrial and microcirculatory function measurements. The focus is on researching alterations in mitochondrial function by means of the Cellular Oxygen METabolism (COMET) monitor, for measuring mitochondrial oxygenation and oxygen consumption in vivo. This is crucial as mitochondrial dysfunction is believed to play a key role in the pathophysiology of aging and frailty. The mitochondrial measurements will be complemented by measurement of microcirculatory parameters in order to get insight in what has recently been defined as the *critical unit*, emphasizing the coalescence and interplay between mitochondria and microcirculation. The hypothesis is that we will find differences in the critical unit between healthy older adults and more vulnerable and frail elderly patients, which can potentially be useful in decision making and patient management.

Study objective

To ascertain differences in mitochondrial and microcirculatory parameters between healthy older adults (> 65 years and ASA1-2) and more vulnerable elderly patients (> 65 years and ASA 3-4).

Study design

A single-center observational study at Erasmus Medical Center's pre-operative clinic

Study burden and risks

Participants will undergo non-invasive procedures with minimal risks, such as mild skin irritation. The study does not offer direct benefits to the participants but aims to enhance perioperative care for the elderly. The burden includes additional blood sampling and standard perioperative measurements. The risks are considered low, mainly involving temporary skin discomfort and standard blood sampling risks. This study is particularly pertinent to the elderly undergoing surgery, aiming to improve their care by better understanding mitochondrial function and microcirculation in the context of frailty and perioperative management

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

> 65 years of age at start of the study
Planned for elective surgery.

Exclusion criteria

• Not able to read or speak Dutch or English;
• Skin defects at the measurement side;
• Mentally disabled;
• Porphyria;
• Presence of mitochondrial disease;
• Medically unsave, or pfysically unable to perform a sit-to-stand test
according to own justment or the justment of the medical staff or the research

team assosiated with this studie

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-06-2024
Enrollment:	94
Type:	Anticipated

Medical products/devices used

Generic name:	COMET
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-06-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2025
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL86239.078.24