Detecting mitochondrial oxygen tension (mitoPO2) with the Cellular Oxygen Metabolism (COMET) measurement system as measure of local tissue oxygenation in patients with peripheral arterial disease – A pilot study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22552

Source
NTR

Brief title
COMPASION

Health condition

Peripheral arterial occlusive disease (PAOD)

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Source(s) of monetary or material Support: 1st flow of funds

Intervention

Outcome measures

Primary outcome

The feasibility and tolerability of mitochondrial oxygenation measurements with the COMET device and Alacare patch in patients with severe claudication (Rutherford class 4-6).

Secondary outcome

• the optimal measurement location for the measurement of mitochondrial oxygen consumption with the best signal quality.
• the influence of application time for the Alacare patch on the signal quality.
• correlation of the COMET device measurements to TcPO2 and ankle brachial index (ABI)
• signal quality in the same place of the Alacare patch after previous use.
• effect of skin temperature on COMET measurements

Study description

Background summary

Peripheral arterial disease (PAD) is a progressive, common disease which is often underdiagnosed. Symptoms of PAD range from asymptomatic to chronic limb-threatening ischemia (CLTI). It is a result of impairment of tissue perfusion, which requires effective diagnosis. Current diagnostic methods only detect stenotic lesions of the major arteries but do not measure tissue perfusion. It is essential to determine tissue perfusion as impaired perfusion of oxygenated blood is the direct cause of the aforementioned symptoms. The golden standard to determine tissue perfusion is transcutaneous partial pressure of oxygen (tcPO2) measurements. Unfortunately, this method is not suited for everyday clinical use during interventions, is operator dependent and time consuming. The COMET system is a non-invasive system to locally determine mitochondrial oxygen availability in human skin cells. Increase of the mitochondrial metabolism may be an early/sensitive indicator for procedure success, even if tissue perfusion is still low. Therefore, it might perform better than TcPO2. Furthermore, the measurement can easily be performed by health professionals in-hospital, and during interventions. This enables the use of this method during the complete care process of patients with peripheral arterial disease such as early and even intraoperative detection of improvement or failure of therapy.

Study objective

COMET measurements are feasible in patients with PAOD and the measurements are tolerable.

Study design

Start: 01/11/2021
Inclusion expected to be completed 01/05/2022, maximum by 01/03/2023

For each subject:
1) The day before the operation (first day):

a) Patient is admitted
b) At 20:00 > One of the trained researchers applies the Alacare patches on the patient
c) Patient is monitored in the ward via an SOP that will be given to the ward nurses

2) The day of the operation (second day):

a) At 08:00 > Measurements with COMET device, TcPO2, and ABI
b) Patient undergoes operation
c) At 16:00 > Measurements with COMET device, TcPO2 and ABI

Contacts

Public
University Medical Centre Groningen
Abdallah Hussam Abdallah Zaid Al-Kaylani

0687827217
Scientific
University Medical Centre Groningen
Abdallah Hussam Abdallah Zaid Al-Kaylani

0687827217

Eligibility criteria

Inclusion criteria

- 55 years and older
- Scheduled for a recanalization/bypass operation
- Written informed consent.
- Claudication, Rutherford class 4-6.
- Healthy skin of the affected limb

Exclusion criteria

- Insufficient knowledge of the Dutch language, illiteracy, or language barrier.
- Lower leg fracture within the past 12 months.
- (Partial) amputation of one of the feet and/or legs.
- Tattoos in location of patches.
- Severe cardiac-pulmonary failure.
- Known hypersensitivity to the active substance or any of the following excipients: patches: acrylic pressure sensitive adhesive (poly[(2-ethylhexyl)acrylate-co-methylacrylate-co-acrylic acid-co-glycidylmethacrylate]), backing film: pigmented polyethylene aluminium vapor coated polyester, and release liner (polyethylene terephthalate film) which is removed prior to application.
- Known diagnosis of porphyria.
- Known photodermatoses of varying pathology and frequency, e.g. metabolic disorders such as aminoaciduria, idiopathic or immunological disorders such as polymorphic light reaction, genetic disorders such as xeroderma pigmentosum, and diseases precipitated or aggravated by exposure to sun light such as lupus erythematoides or phemphigus erythematoides.
- Diabetes.
- Previous photodynamic therapy or recent use of a tanning bed.
- Subjects using medicinal products with known phototoxic or photoallergic potential such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones and tetracyclines.
- Use of other topical medicinal products.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	20

Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9853
Other	METC UMCG : METc 2021/539

Study results