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

Gepubliceerd: 27-10-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22552

Bron
NTR

Verkorte titel
COMPASION

Aandoening

Peripheral arterial occlusive disease (PAOD)

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
Overige ondersteuning: 1st flow of funds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

University Medical Centre Groningen
Abdallah Hussam Abdallah Zaid Al-Kaylani

0687827217

Wetenschappelijk

University Medical Centre Groningen
Abdallah Hussam Abdallah Zaid Al-Kaylani

0687827217

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	20

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9853
Ander register	METC UMCG : METc 2021/539

Resultaten