The influence of hemodialysis and vascular access surgery on systemic circulation and microcirculation: a validation study

Published: 16-04-2018
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Primary objective* To investigate the correlation between cutaneous microcirculation (using LSCI), finger and toe pressures and shunt flow in hemodialysis patients.Secondary objectives* To investigate the variability in basal flow measured with LSCI...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational non invasive

Summary

ID

NL-OMON48972

Source
ToetsingOnline

Brief title
(Micro)circulation in hemodialysis patients

Condition

- Nephropathies
- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
Dialysis, Hemodialysis

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Centre for Human Drug Research

Intervention

Keyword: Hemodialysis, Microcirculation, Systemic circulation

Outcome measures

Primary outcome

* correlation of finger and toe pressures with LSCI and shuntflow measurements

Secondary outcome

* Variability of microcirculation measured with LSCI in hemodialysis patients.

* Association between shuntflow and basal blood flow measured with

microcirculation measurements using LSCI

* * LSCI (blood flow upon occlusion/reperfusion) and shunt flow

* Effect of a hemodialysis session on finger and toe pressures and LSCI basal

blood flow

* Correlation between blood flow upon occlusion/reperfusion (endothelial

function) using LSCI in hemodialysis patients and retrospective good/poor AVF

maturation.

Study description

Background summary

Arteriovenous fistulas (AVF*s) or arteriovenous grafts (AVG*s) are used commonly as vascular access for maintenance hemodialysis. From retrospective series, case series and animal studies it is known that the creation of a AVF or AVG results in a certain systemic steal and compromise cardiac function. However, it is yet unknown in what extend this is and if there are any risk

factors to develop systemic steal and subsequent cardiac problems. Therefore, the aim of the present study is to get more insight in the influence of hemodialysis and the creation of an AVF or AVG on systemic (micro) circulation. Additionally endothelial dysfunction, and therefore probably microcirculation, plays a role in failure to mature in AVF surgery. A recent study show that microcirculation measured with infrared thermal imaging (FLIR) can predict maturation in AVF surgery.
This study will be used to measure the variability in microcirculation measured with LSCI in hemodialysis patients. This validation study is performed as preparation of a future study in which we want to measure pre- and postoperative micro-circulation prospectively in patients that undergo vascular access surgery, to investigate the influence of an AVF/ AVG on micro-circulation, and secondly if in the future LSCI could be used as a predictor for AVF maturation.
In conclusion this study is a validation study of LSCI micro-circulation measurements in hemodialysis patients and can be used for a future power calculation for our planned prospective study.

Study objective

Primary objective

* To investigate the correlation between cutaneous microcirculation (using LSCI), finger and toe pressures and shunt flow in hemodialysis patients.

Secondary objectives

* To investigate the variability in basal flow measured with LSCI in hemodialysis patients
* To investigate the variability in * LSCI (using occlusion/reperfusion measurements) in hemodialysis patients
* To investigate if microcirculation with occlusion/reperfusion measurements (expressing endothelial function) measured with LSCI in hemodialysis patients is correlated to good/poor AVF maturation (using retrospective data)

Study design

Open observational multicentre study

Study burden and risks

This is an observational study without pharmacological or surgical intervention. The primary assessments that the study participants will undergo are measurement of standard vital parameters, finger and toe pressure measurements and vascular function measurements by LSCI, with temporary occlusion (of the brachial artery or index finger). These are

non-invasive methods, commonly applied in human studies on vascular functionality, with a negligible risk for the study participants.
Occlusion/reperfusion measurement will only be performed on the contralateral (non-shunt) arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All subjects must be able to participate and be willing to give written informed consent and to comply with the study restrictions. In addition, eligible subjects must meet the following inclusion criteria:;- Patients male/female > 18 years old that are on hemodialysis using an arteriovenous fistula (AVF) or arteriovenous graft (AVG) and are capable of giving written informed consent.

Exclusion criteria

1. Concomitant disease or condition that could interfere with the conduct of the study or the study objectives, or that would, in the opinion of the investigator, pose an unacceptable risk to the study participant.
2. Condition of the skin that prohibits accurate LSCI measurements, such as large tattoos, skin ulcers, scar tissue, etc.
3. For group 2: prior vascular access surgery on contra or ipsilateral arm.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	16-04-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-04-2019

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL64651.098.18