Sidestream dark field imaging of the sublingual microcirculation for the assessment of edema formationas indicated via cumulative fluid balance

Published: 13-01-2014 Last updated: 24-04-2024

to investigate the relationship between the SDF-microscope focal setting necessary to obtain a sharp image of the sublingual microcirculation and the extent of edema formation, as indicated via cumulative fluid balance

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

Summary

ID

NL-OMON40488

Source ToetsingOnline

Brief title SDF and edema/ fluid balance

Condition

Other condition

Synonym

edema, tissue fluid accumulation

Health condition

patienten opgenomen op IC, na electieve chirurgie of acuut (dan niet gespecificeerd welke catagorie)

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Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: edema, fluid balance, microcirculation

Outcome measures

Primary outcome

focal point of SDF microscope

recorded fluid balance at time of SDF imaging

Secondary outcome

admission category and electivity

clinical signs of edema formation

weight if measured

bio-impedance if measured

SOFA score

albumin

fluid therapy specified to type (0.9% NaCl, lactated ringer, gelofusin,

albumin, blood products, glucose)

Study description

Background summary

Edema, the accumulation of fluid in the interstitial space, is seen in a wide range of disorders and is caused by either changes in oncotic- and/or

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hydrostatic pressures, impaired fluid drainage by the lymphatics or excessive leakage from the vasculature due to increased vascular permeability. Measuring edema is not straightforward. The most used method is that of keeping record of all fluids going in and out of the patient, the fluid balance. A positive net fluid balance indicates edema formation, but this is hardly a precise method. We hypothesize that the accumulation of interstitial fluid is directly related to the focal setting needed to acquire a sharp image with the SDF microscope used for imaging the sublingual microcirculation.

Study objective

to investigate the relationship between the SDF-microscope focal setting necessary to obtain a sharp image of the sublingual microcirculation and the extent of edema formation, as indicated via cumulative fluid balance

Study design

observational

Study burden and risks

no benefit for the patient, very minimal burden, with no additional risks

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

age: 18 y and older admittance to the intensive care unit elective surgery OR medical or surgical patients with emergency admittance and expected intubation period over 24 hours at least one sharp SDF recording (per timepoint),

Exclusion criteria

influences that would severely reduce the accuracy of the recorded fluid balance (i.e. internal or external bleeding, incomplete fluid registration) intra-oral bleeding

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL Recruitment status:

Recruitment stopped

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Start date (anticipated):	22-01-2014
Enrollment:	60
Туре:	Actual

Ethics review

Approved WMO	
Date:	13-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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 CCMO

ID NL47067.029.13