Evaluation of effect of fluidrescucitation on sublingual microcirculation by SDF imaging in Intensive Care patients, a pilot study

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Objective: Is fluid responsiveness, what means a better cardiac output, equal to the need for fluid for a better organ perfusion?In hospital we now looking to the pumpfunction of the heart, we don't have a better measurement. However this gives...

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

Summary

ID

NL-OMON34514

Source
ToetsingOnline

Brief title
Effect of Fluidresucitation and microcirculation

Condition

- Other condition

Synonym
fluid responsiveness, microcirculation

Health condition

microcirculatie

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Intensive Care Onderzoek Leeuwarden

Intervention

Keyword: fluid responsiveness, Intensive Care, microcirculation, SDF

Outcome measures

Primary outcome

- correlation between delta MFI and fluid responsiveness

- delta MFI before and after fluid challenge correlated to fluid responsiveness

Secondary outcome

- delta capillary density correlated to fluid responsiveness

Study description

Background summary

Although we do al lot of measurments to monitor the fluidstate of the patients, we don't know exactly weather the fluid has real effect on the organ perfusion. The main focus of fluid is to improve the organ perfusion. Recent research has focused on the investigation of sublingual microcirculatory alterations.

Study objective

Objective: Is fluid responsiveness, what means a better cardiac output, equal to the need for fluid for a better organ perfusion?
In hospital we now looking to the pumpfunction of the heart, we don't have a better measurement. However this gives no information about necesity of giving fluids.. A healthy volunteer also gives a better pumpfunction of the heart after fluid, but that fluid is not necessary and gives no better organperfusion.
The question is: Howmany percent of the patients have a MFI score of < 2.6 when the doctor on clinical basis plans to give fluid to the patient. Improves organ perfusion after fluid and is this correlated with an improvement of the cardiac

output

Study design

All intensive care patients who need extra fluid are eligible for this stduy.
Before and after the fluid challenge we do SDF imaging sublingual. Per patient we do this 1x in 24 hours.
Concurrently, data on both patient characteristics (e.g. severity of illness) will be obtained
Studypopulation max 100 patients.

Possible outcome:
MFI < 2,6 en SV > 10% + MFI up
MFI < 2,6 en SV gelijk + MFI equal
MFI < 2,6 en SV > 10% + MFI equal
MFI < 2,6 en SV gelijk + MFI up
MFI > 2,6 en SV > 10% + MFI up
MFI > 2,6 en SV gelijk + MFI equal
MFI > 2,6 en SV > 10% + MFI equal
MFI > 2,6 en SV gelijk + MFI up

Study burden and risks

Non invasive measurement, no damaging consequences have been observed

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

admission on ICU
> 18
fluid neccesary

Exclusion criteria

< 18
geen informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL34394.099.10