Optimization of the hypothermia procedure in the ICU - the influence of bodycomposition on the succesful performance of therapeutic hypothermia

Published: 24-11-2006
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The purpose of this study is to do research what the effect of the BMI and fat percentage is on the speed of cooling.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON30238

Source
ToetsingOnline

Brief title
Bodycomposition of cooled patients

Condition

- Cardiac arrhythmias

Synonym
forced cooling, induced hypohermia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anthropometrics, Bodycomposition, hypothermia, Out-of-Hostpital-Cardiac-Arrest

Outcome measures

Primary outcome

nnb

Secondary outcome

nnb

Study description

Background summary

Patients with an out of hospital cardiac arrest has a poor neurological outcome. According to three studies, these patients benefits from mild induced hypothermia. The speed of cooling is very important, but there is a large spreading in time (2 to 8 hours) reaching the target temperature due to difference in underlying desease, age, sexe and bodycomposition (anthropometrics). However that it is obvious that bodycomposition is related with speed of cooling, little has done to quantify this relationship and so the operation of cooling made researchable.

Study objective

The purpose of this study is to do research what the effect of the BMI and fat percentage is on the speed of cooling.

Study design

The following data is collected standard:
-length
-weight
The next data is collected especially for this study:
-standard anthropometric measurements are performend 3 times (4 point-skinfold thickness, mean is used for analysis)
-circumference of upperarm and waiste, skinfold thickness of bicep is used to compute fatarea and muscle area.
-bonemass is computed from the condyl width
-Impedance is measured 3 times within the period of cooling, with an interval

of 15 minutes

Study burden and risks

The measurements are being performend at sedated patients; none of the especially for this study performend measurements are stressfull for the patients. For the last examination (impedance) the patients becomes two extra ecg electrodes on the hand and foot. This measurement is also not stressful. The patient is retrogressive informend about this extra measurements.

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

consecutive patients admitted to the ICU after out of hospital cardiac arrest who are to be in which the decision is made to start hypothermia
age > 18 years

Exclusion criteria

Patients who's body weight cannot be measured

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	ID
CCMO	NL15044.018.06