Early cooling of the brain using burn dressings
-a proof of concept observation-

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To determine the effect of the application of burn dressings on the skin of face and neck on the tympanic temperature of healthy volunteers.

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

Summary

ID

NL-OMON29829

Source
ToetsingOnline

Brief title
Burning Issues

Condition

- Other condition
- Encephalopathies

Synonym
cardiac arrest, heart attack

Health condition

circulatiestilstand

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain cooling, Prehospital, Resuscitation

Outcome measures

Primary outcome

Changes in tympanic temperature expressed in degrees Celsius and measured by

non-invasive Infra-Red thermometer

Secondary outcome

Not applicable

Study description

Background summary

Early cooling of resuscitated patients improves neurological outcome. The beneficial effect of cooling is primarily caused by lowering the cerebral metabolism by reduction of the brain temperature. this effect is enhanced by the early initiation of the cooling. Prehospital cooling however is uncommon for mainly practical reasons. Using burn dressings to initiate cooling in the prehospital care could be of value and is easily adaptable by ambulance crews. The influence of burn dressings on brain temperature is however unknown

Study objective

To determine the effect of the application of burn dressings on the skin of face and neck on the tympanic temperature of healthy volunteers.

Study design

Proof of concept observation

Study burden and risks

Considering the non invasive nature of the intervention, measurements and the absence of other chemical compounds than water and a vegetable oil (Melaleuca alternifolia) in the dressings used, the burden and discomfort to the study subjects (if any) is expected to be minor. People with allergies tot Melaleuca alternifolia or plants of the Myrtaceae family may be more likely to show allergic reactions as rashes and skin swelling, although literature provides only case reports of application of the substance to affected skin. No literature addressing adverse events of the cutaneous use of Melaleuca alternifolia is available.

There is no potential benefit to the study subjects other than the possible skin-smoothening effects of the combination of water and Melaleuca alternifolia.

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

Healthy volunteers, aged > 18 years
Written consent to participate in the experiment and to endure the expected discomfort of the application of cooling compresses on the skin of face and neck.

Exclusion criteria

Current treatment by a physician or medical specialist.
Active dermatologic condition of the face and/or neck region
Known allergy to Melaleuca alternifolia (Tea tree Oil)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	10
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	NL12151.018.06