Effectiveness of heat blankets in preventing hyperthermia in Dutch military personnel

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The objective of the study is to determine the effectiveness of three types of heat blankets in reducing the cooling rate of the human body in arctic conditions

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51723

Source
ToetsingOnline

Brief title
Effectiveness of heat blankets

Condition

- Other condition

Synonym
Cold body, low body temperature

Health condition

Hypothermie

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Defensie, Staf Commando Landstrijdkrachten
Source(s) of monetary or material Support: Financiering wordt door Defensie zelf verzorgd.

Intervention

Keyword: Basic Life Support, Core temperature, Hypothermia, Military

Outcome measures

Primary outcome

The primary outcome of this study is the change in core body temperature during a period of four hours in which subjects will lay on a mattress in a climatic room with a temperature of minus 30 degrees Celsius. During this period they are wearing winter clothing and will be tucked in in one of the three heat blanket configurations.

Secondary outcome

Secondary study outcomes are mean skin temperature, heart rate, thermal sensation, and thermal comfort.

Study description

Background summary

In an extremely cold environment, Dutch soldier have to be able to remain safe for four hours when they do not have the possibility to move themselves. To do so, they carry heat blankets along in their equipment. To make an informed decision on which heat blankets are suitable for this purpose, information is needed on the effectiveness of three commonly used heat blankets

Study objective

The objective of the study is to determine the effectiveness of three types of heat blankets in reducing the cooling rate of the human body in arctic

conditions

Study design

The study has a within subject design with repeated measurements. Each subject will conduct three experimental sessions and in each session another heat blanket will be used.

Intervention

The intervention consists of three distinct configurations of heat blankets. Configuration A is the Blizzard Survival Blanket. Configuration B is the Blizzard Survival Blanket plus four Blizzard A5 heating pads. Configuration C is the Blizzard Survival Blanket plus the Ready-Heat full body temperature management blanket.

Study burden and risks

The subjects will visit the climate testing room in Woensdrecht 3 times a week. During these visits they will be exposed to a temperature of -30°C for 4 hours - wrapped in winter clothing and a heat/insulation blanket. During this period, the body temperature will be continuously measured with a thermo capsule, skin temperature will be measured with small buttons and heart rate will be measured with a monitor worn around the upper arm. The subjects also give a score for thermal sensation and thermal comfort every half hour. The risks when using the heat/insulation blankets are minimal as they are CE-certified products that are used in accordance with the regulations. The risk of hypothermia is minimized by the continuous monitoring of body temperature. When a subject reaches a body temperature of * 35.0°C (the limit of mild hypothermia), the subject is taken out of the cold and warmed up with hot drinks. The risk of frostbite injury is minimized by thoroughly covering the skin with clothing. The main risk associated with the use of the measuring devices is the oral ingestion of the telemetric temperature pill. This is not a problem for people without gastrointestinal disorders and the pill leaves the body again naturally within 12-36 hours. Measures are taken to ensure that the subjects do not undergo an MRI scan while they still have the telemetric pill within their body. This is done by emphasizing the danger of this and by making it mandatory to wear a plastic bracelet stating that the subject has a telemetric pill in his/her body. In summary, the risks of participating in this study are very minimal. The subjects do not receive any compensation for participating in the study. They can experience how their body reacts to extreme cold, which can be useful in the future. They also contribute to obtaining well-functioning equipment for arctic training and deployment, which benefits the entire organization.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Military personnel or military students aged 18-65

Exclusion criteria

- History with cold-related injuries
- Syndrom of Raynaud
- Coronaryvascular disease
- Diabetes Mellitus 1/2
- Peripheral vascular disease
- Hyperhydrosis
- Hypothyroidism
- Use of betablockers or vasconstrictors

- GI disease or surgery

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Heat blankets
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-03-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL79889.028.22