Is preventing hypothermia in patients undergoing a primairy Total Knee Prosthesis or Total Hip prosthesis with the Barrier Easywarm as effective as with Forced-Air Warming.

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If there is comparable Efficacy in preventing hypothermia we can start using the barrier easywarm instead of the BairHugger. With the Bair hugger there is a disruption in airflow in the operatieon theatre which might bring a higher risk of infection...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45308

Source
ToetsingOnline

Brief title
Comparable Efficacy in Orthopedic Patients?

Condition

- Bone and joint therapeutic procedures

Synonym
Hypothermia Patientheating

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Ziekenhuis

Intervention

Keyword: Bair Hugger, Barrier easywarm, Forced air warming, Hypothermia

Outcome measures

Primary outcome

Temperature during operation.

Secondary outcome

NVT

Study description

Background summary

Prevention of hypothermia in patients undergoing a primairy Total Knee Prosthesis or Total Hip prosthesis. We want to investigate if the Barrier Easywarm is as effective as with the Forced-Air Warming.

Study objective

If there is comparable Efficacy in preventing hypothermia we can start using the barrier easywarm instead of the BairHugger.
With the Bair hugger there is a disruption in airflow in the operatieon theatre which might bring a higher risk of infection.

Study design

Randomized Controlled Trial, non inferiority study

Intervention

40 patients will be randomized in the barrier Easywarm group, the other 40 in the Bairhugger group.
During the operatieon the core temperature will be measured by the 3M SpotOn

monitoring system

Study burden and risks

Both warming systems are already used in operating theatres.

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

Patients undergoing total hip or knee prosthesis

Exclusion criteria

severe arterial disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60416.098.16