Afdrukken in de huid, huidtemperatuur en comfort van twee nekkragen

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28715

Source
Nationaal Trial Register

Health condition

Related to the cervical collars:

- Indentation marks
- Skin temperature
- Comfort
In dutch: indentatieletsel, huidtemperatuur en comfort.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Indentation marks divided in: none, mild and severe.

Secondary outcome

Skin temperature measured in degree celsius and experienced comfort on a 5-point Likert scale

Study description

Background summary

Background

Trauma patients who are immobilized with a cervical collar for preventive reasons, are at risk for developing collar related pressure ulcers (CRPU). There is a possibility that the Philadelphia cervical collar (C- collar) is a more favourable alternative for preventive immobilization using the Stifneck C-collar in trauma patients. However, the influence of risk factors for CRPU in the latest versions of these C-collars remains unclear due to lack of recent studies. Besides the patients' condition, produced pressure, fit of the medical device and increased skin temperature seem relevant risk factors. It is possible that comfort and indentation marks (IM) are a sign of the exerted pressure and fit of the C-collar.

Aims

Primary Objective is to evaluate the effect of the Stifneck and Philadelphia cervical collar on incidence and severity of IM in immobilized healthy volunteers. Secondary Objectives are to evaluate the effect of the Stifneck and Philadelphia cervical collar on skin temperature and experienced comfort in immobilized healthy volunteers.

Design

Single-blinded randomized controlled trial.

Population

Healthy human volunteers from eighteen till 65 years old.

Intervention

One group receives the Stifneck C-collar and the other group receives the Philadelphia C-collar. Both groups are immobilized for 20 minutes in the C-collar.

Main study parameters

The main study parameter is the incidence of IM at the end of the immobilization time divided in no, mild or severe IM. In addition, skin temperature is measured by an infrared thermometer and experienced comfort is assessed by a five-point Likert scale.

Analysis

Difference between groups for the main parameter is tested by a Chi-square test. Secondary parameters are tested on differences by unpaired sample T-test and Chi-square test.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

Participants have one site visit of about 30 minutes. There are no risks while participating in the study.

Study objective

There is a possibility that the Philadelphia neck collar gives better results than the stifneck collar on the proposed outcomes.

Study design

T0: before immobilization in the cervical collar

T1: after 20 minutes of immobilization in the cervical collar

Intervention

1. Laerdal Stifneck cervical collar

2. Philadelphia Tracheatomy cervical collar

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers

18 till 65 years old

Speak and read the Dutch language

Exclusion criteria

Wound on and around the neck area, dermatologic diseases, blood circulation or pulmonary disorders, Diabetes Mellitus type I or II, previous spinal injuries or surgery, osteoporosis or spondylosis, use of analgesics in the past 24 hours, current neck pain, current pregnancy and chiropractic or physical therapy in the past six weeks.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-01-2018
Application type:	First submission

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
NTR-new	NL6793

Register	ID
NTR-old	NTR6979
Other	METC-protocolnummer : 17-912/C

Study results