Early detection of pressure ulcers in individuals with a complete spinal cord injury

Published: 18-06-2015
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To determine if a marked change in the concentrations of one or more of the selected biomarker is evident before PUs are visible

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44664

Source
ToetsingOnline

Brief title
Early detection of PU

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
pressure sores, Pressure ulcers

Health condition

Decubitus

Research involving
Human

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven
Source(s) of monetary or material Support: Stichting Techniek en Wetenschap

Intervention

Keyword: Decubitus, Pressure ulcer, Spinal cord injury

Outcome measures

Primary outcome

The concentration of several biomarkers in urine.

Secondary outcome

To determine possible causes for changes in biomarker concentration not

associated with a PU.

Study description

Background summary

Individuals with a spinal cord injury are at high risk for developing a pressure ulcer (PU) due to immobility and lack of sensation. The first step in treating PUs is pressure relieve, which can lead to the patient becoming bedbound. It is hypothesized that due to degradation of soft tissue (e.g. skin, muscle) several biomarkers are released into the bloodstream and subsequently excreted in urine before the PU is visible. These markers can be used in an early detection method aimed at earlier treatment of PUs. The first step in this method is non-invasively screening high risk individuals. If an indication of PU development is made further diagnostics (e.g. MRI, ultrasound) should identify the area at risk. The aim of this study is to determine the suitability of several biomarkers for monitoring PUs. Normal values of the markers in urine are currently unknown for individuals with a spinal cord injury (SCI). An exploratory study will be performed to ascertain baseline variability. An extended study will be performed to determine changes in biomarker concentration before PUs are visible.

Study objective

To determine if a marked change in the concentrations of one or more of the

selected biomarker is evident before PUs are visible

Study design

A prospective cohort study

Study burden and risks

At the start of the exploratory study an initial interview will be held with the participants. A pin prick will be collected to exclude patients with an active infection. Over a period of 8 weeks participants will collect daily morning urine samples and fill in a questionnaire. The risks associated with blood sampling are minimal.
At the start of the extended study an initial interview will be held with the participants. Over a maximal period of 2 years participants will fill in a questionnaire and collect a urine sample every 4 weeks. Development of a PU (excluding category I) necessitates daily urine sampling and daily submitting of a questionnaire for a week, after which the study will end. Unexplainable fever, indicative for deep tissue injury, necessitates daily urine sampling and daily submitting of a questionnaire until the cause of the fever is determined, the fever has resolved or a pressure ulcer is detected. The extended study has no risks. The participants are mainly burdened by the time it takes to fill in the questionnaire, collect the urine samples and hand in the urine sample

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

Group 1
* Adult
* Have a sensory and motor complete lesion, ASIA A between L1 and C4
* Lesion acquired less than 1 year ago
* Possible to collect a non-contaminated urine sample (e.g. naturally controlled urination, clean intermittent catheterisation, indwelling catheter with a sample port)
* Signed informed consent ;Group 2+4
* Adult
* Have a sensory and motor complete lesion, ASIA A between L1 and C4
* Lesion acquired over 1 year ago.
* Possible to collect a non-contaminated urine sample (e.g. naturally controlled urination, clean intermittent catheterisation, indwelling catheter with a sample port)
* Signed informed consent ;Group 3
* Adult
* In good health
* Signed informed consent

Exclusion criteria

All groups
* Mental disability that hinders the ability to understand and comply with the informed consent
* Diagnosed skin disease
* Oncological patients
* If a subject is unable to obtain urine samples themselves and do not have assistance.
* Fever (temperature > 38*C) will lead to temporary exclusion
* Have had a pressure ulcers diagnosed in the past 6 months.;Extra exclusion criteria for group 1+2+3
* Active infections at the start of the study (determined by POCT CRP) will lead to temporary exclusion
* If a subject in the home situation does not have the ability to store samples at minus 20*C.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2015
Application type:	First submission
Review commission:	METC Catharina Ziekenhuis (Eindhoven)
Approved WMO Date:	26-05-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	16-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL52521.060.15

Study results

Date completed:	24-04-2018
Actual enrolment:	18