Elastography of soft tissue under high risk for deep tissue injury type of pressure ulcers

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To gain more insights in the mechanical properties of soft tissue under high risk for deep tissue injury type of pressure ulcers with US and MR Elastography.

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

Summary

ID

NL-OMON42849

Source
ToetsingOnline

Brief title
PrU-SCI-MRE

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
pressure sores, pressure ulcer

Health condition

Decubitus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Techniek en Wetenschap

Intervention

Keyword: Decubitus, Elastography, Pressure Ulcer, Spinal Cord Injury

Outcome measures

Primary outcome

Mechanical properties of soft tissue susceptible for the onset to deep tissue

injury.

Secondary outcome

* Compare the mechanical properties of the gluteus muscles in healthy and SCI

individuals with US and MR Elastography

* Investigate the reproducibility of muscle mechanical properties measurements

with both US and MR Elastography in healthy volunteers

* Investigate the correlation of muscle mechanical properties measurements

found with US and MR Elastography in healthy volunteers

Study description

Background summary

A spinal cord injury (SCI) is accompanied with alterations in muscle properties and it is expected that these pathological transformations go together with changes in tissue mechanical properties. This induces elevated pressure and shear stresses to soft tissue, and make them prone for developing deep tissue injury. Mechanical properties of soft tissue will be examined as predictors for deep tissue injury development.
Elastography is a method that is capable of quantifying tissue mechanical properties and can either be performed with ultrasound (US) or Magnetic Resonance (MR) modalities. Therefore, elastography (US and MR) will be used to

study muscle mechanical properties in gluteus muscles of healthy subjects versus individuals with a spinal cord injury. An exploratory study will be performed to investigate the feasibility of the elastography technique and to ascertain the difference and variability in muscle mechanical properties of healthy subjects and subjects with spinal cord injury.

Study objective

To gain more insights in the mechanical properties of soft tissue under high risk for deep tissue injury type of pressure ulcers with US and MR Elastography.

Study design

Prospective, exploratory cohort study

Study burden and risks

The study is completely non-invasive and no contrast agents will be administered. The participant*s main burden is the time it takes to visit the AMC and/or Spinoza Center. The participants in the study take part once. For the individual participant, US and/or MRI could result in unexpected findings of deep tissue injury that may require further work-up. Participants and their general practitioner will be informed about this. The potential value of this study is that more knowledge in the aetiology of deep tissue injury will be obtained, resulting the development of a reliable diagnostic method based on elastography for early detection of deep tissue injury. This will ultimately benefit all patients who are in high risk for development of deep tissue injury type of pressure ulcers.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* 18 years of age or older
* The capacity to understand the patient information sheet and the ability to provide written informed consent.;Healthy controls (group 2)
* will be matched in adapted BMI (adapted in scale to match Spinal Cord Injured in equivalent way), sex and age with spinal cord subjects in group 3 of this study.;Spinal Cord Injured group (group 3):
* Lesion of lower than vertebra C5. People with higher level lesions suffer from respiratory problems and need external ventilators. These ventilators are not MR compatible.
* Lesion acquired three months ago and longer. People with a more recent Spinal Cord Injury are in spinal shock period and still in rehabilitation.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Standard contraindications to MR imaging (e.g. cardiac pacemaker, cochlear implant, claustrophobia, pregnancy).
SCI group (group 3):
In case of known MR compatible implants and/or pump in body: extra check will be performed to verify specific implant with Reference Manual for Magnetic Resonance Safety, Implants, and Devices. If check is negative, subject is excluded.
* Waist / Shoulder width larger than 70 cm (diameter of MR scanner)
* Suffer from a current pressure ulcer.
* Medical history with respect to muscular diseases

Study design

Design

Study type:	Observational non 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):	01-04-2017
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2016
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	NL56835.018.16