

# Cost-effectiveness of the Australian medical sheepskin for the prevention of pressure ulcers in somatic nursing home clients

<b>Submission date</b>	<b>Recruitment status</b>	[X] Prospectively registered
08/02/2007	No longer recruiting	[X] Protocol
<b>Registration date</b>	<b>Overall study status</b>	[ ] Statistical analysis plan
08/02/2007	Completed	[X] Results
<b>Last Edited</b>	<b>Condition category</b>	[ ] Individual participant data
04/07/2011	Skin and Connective Tissue Diseases	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

## **Study objectives**

Research questions are:

1. What are the effects of appliance of Australian Medical Sheepskins on the incidence and prevalence rates of sacral pressure ulcers in somatic nursing home clients in the first month after admission compared to usual care?
2. What are the costs of appliance of Australian Medical Sheepskins compared to usual care?
3. What are the costs of the treatment for eventually developed pressure ulcers in the two study groups?
4. What adverse effects do Australian Medical Sheepskins have?
5. How do patients and nursing and caring personnel rate the (dis)comfort of Australian Medical Sheepskins and the ease of use of Australian Medical Sheepskins?

For this study we will consider the Australian Medical Sheepskin as effective if the incidence rate in the first month after admission is at least (absolute) 10% less in the experimental group than in the control group and the prevalence numbers at two moments during the research period are (absolute) 10% lower in the experimental group than in the control group.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approval received from the local ethics committee (METC Universitair Medisch Centrum Utrecht) on the 2nd January 2007 (ref: NL14075.041.06).

## **Study design**

Randomised, active-controlled, parallel group multicentre trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Pressure ulcers

## **Interventions**

Australian Medical Sheepskin plus usual care during first 30 days after admission to a nursing home versus usual care only.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

1. Incidence and prevalence of pressure ulcers on the sacrum in the first month after admission
2. Costs

**Key secondary outcome(s))**

1. Sacrum pressure ulcer free days
2. Adverse events
3. Comfort/ease of use

**Completion date**

01/11/2008

## Eligibility

**Key inclusion criteria**

1. Adults
2. Admitted for a somatic reason
3. Free of sacral pressure ulcer
4. Not having a darkly pigmented skin (because of difficulty to diagnose stage one ulcer)
5. Having an expected stay of more than one week

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

1. Admitted for a primarily pyscho-geriatric reason
2. Having sacral pressure ulcers at admission

**Date of first enrolment**

01/05/2007

**Date of final enrolment**

01/11/2008

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

# Netherlands Institute for Health Services Research (NIVEL)

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## Sponsor information

### Organisation

Netherlands Institute for Health Services Research (NIVEL) (The Netherlands)

### ROR

<https://ror.org/015xq7480>

## Funder(s)

### Funder type

Research organisation

### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2011		Yes	No
<a href="#">Protocol article</a>	protocol	07/01/2008		Yes	No