

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

Submission date 08/02/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 08/02/2007	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 04/07/2011	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Patriek Mistiaen

Contact details
Netherlands Institute for Health Services Research (NIVEL)
P.O. Box 1568
Utrecht
Netherlands
3500 BN
+31 (0)30 272 9779
p.mistiaen@nivel.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2007

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

Age group

Adult

Sex

Not Specified

Target number of participants

750

Key exclusion criteria

1. Admitted for a primarily psycho-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)

Utrecht

Netherlands

3500 BN

Sponsor information

Organisation

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

Sponsor details

P.O. Box 1568

Utrecht

Netherlands

3500 BN

+31 (0)30 272 9700

receptie@nivel.nl

Sponsor type

Research organisation

Website

<http://www.nivel.nl/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	07/01/2008		Yes	No
Results article	results	01/11/2011		Yes	No