Recognising Effective Materials By Randomising & Assessing New Donorsite Treatments

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This trial will compare the effectiveness and possible adverse effects of five common wound dressing materials to treat donor sites of split skin grafts.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33029

Source
ToetsingOnline

Brief title
Rembrandt trial

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
donor sites of split skin grafts

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Brandwondenstichting

Intervention

Keyword: bandages, donor site, skin transplantation, wound healing

Outcome measures

Primary outcome

Primary objective is to promote wound healing.

Secondary outcome

Secondary objectives are pain, comfort, infection rate, and costs.

Study description

Background summary

To date there is a large variability in wound dressings regarding the local treatment of donor site wounds after split skin grafting. This is detrimental to the uniformity and quality of care for such patients.

Study objective

This trial will compare the effectiveness and possible adverse effects of five common wound dressing materials to treat donor sites of split skin grafts.

Study design

Multicentre randomised clinical trial with five study arms.

Intervention

Five different wound dressing materials will be compared, namely an alginate, a film, a hydrocolloid, a paraffin gauze, and a silicone dressing.

Study burden and risks

The dressing materials used in this trial are already commercially available and therefore do not pose an extra risk. Patioents will be aked to score their pain, itching and comfort with respect to the dressing material used.
Patients may benefit from participating because they may receive a dressing material that has advantages, for example in terms of a quicker wound healing

or more pain relief.

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

Adults
Condition requiring split skin grafting
Donor site of at least 10 cm2
Written informed consent.

Exclusion criteria

Patients physically or mentally not able to give informed consent
Patients with an impaired wound healing, e.g. undergoing chemotherapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	250
Type:	Anticipated

Medical products/devices used

Generic name:	Wound dressing materials
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL28456.018.09