The effects of Suprathel® versus a calcium alginate on pain perception and comfort in split-thickness skin graft donorsites.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON35254

Source
ToetsingOnline

Brief title
Suprathel® versus a calcium alginate on the STSG donorsite.

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Donor wound, skin transplant wound

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Comfort, Pain, Split-thickness skin graft donor site, Wound dressings

Outcome measures

Primary outcome

The main study parameter is the difference in pain experience and comfort

between Suprathel® and a calcium alginate.

Secondary outcome

Secondary study parameters are the differences in costs, scarring and itching

of scar tissue between Suprathel® and a calcium alginate.

Study description

Background summary

Calcium alginates are frequently used as wound dressings to cover up split-thickness skin graft (STSG) donor sites. The main disadvantage of calcium alginates is the amount of pain experienced on the donor site during mobilization and change of dressings.
Nowadays many new dressings are available. They all claim to decrease the donor site pain during mobilization, but only one primary dressing, Suprathel®, does not require dressing changes and can therefore decrease pain during change of dressings. This research will try to answer the question, whether or not Suprathel® can decrease donor site pain and increase comfort with regard to calcium alginates.

Study objective

The primary objective of this research is to compare pain experience and comfort when a calcium alginate or Suprathel® is used on the donor site.
Secondary objectives are the differences in scarring, itching of the scar

tissue and costs involved with the use of one of both dressings.

Study design

Single centre randomised controlled trial.

Intervention

After randomization half of the number of donor sites will be bound with Suprathel® and the other half with a calcium alginate.

Study burden and risks

No (serious) adverse events are to be expected in the use of both bandages.
From the moment of surgery until discharge the patient will undergo a VAS score for pain and comfort and a short survey once a day. Furthermore the patiënt needs to fill in an EQ5D survey daily.
After discharge the patient will receive a patient diary. The patient will need to fill in a pain and comfort survey and an EQ5D survey in this dairy, once a day, until day 14 after surgery.
When the donor site wound is completely cured, the patient will need to fill in a survey, once a week, up to four weeks. This survey needs to point out, whether or not the patient still feels pain in the donor site and, if applicable, the patient will need to fill in two more pain scores. When the patient does not experience pain, the patient needs to answer the question, whether or not itchiness is experienced in the donor site and, if applicable, the patient will need to fill in two itch scores.
A follow-up appointment will be planned 3 months after surgery. During this appointment the donor site will be assessed on scar tissue and one more pain or itch score will be done.
This complete research will cost the patient a maximum of 2 hours and 15 minutes, exclusive of travel time. Travel time will be compensated.

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

The patient is 18 years or above.
A STSG will be harvested from the patient's upperleg.
The patient signed the informed consent form.

Exclusion criteria

The STSG is harvested from any area other then the upperleg.
The STSG is harvested from a previous donorsite.
The patient has any mental limitation, which will compromise parts of the research.
The patient has any known allergies for one of the wound dressings or their ingredients.
The patient is not able to perceive pain, due to any sensibel impairment.
On medical grounds, the patient should not be treated with adrenaline dressings.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-07-2010
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	wound dressing Suprathel®
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-02-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL28732.078.09