A randomized clinical trial on the effectiveness, cost-effectiveness and quality of life of Flaminal® versus Flammazine® in the treatment of superficial and deep partial thickness burns.

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To evaluate the effectiveness, cost-effectiveness and quality of life of Flaminal® versus Flammazine® in the treatment of superficial and deep partial thickness burns.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40281

Source
ToetsingOnline

Brief title
Flam study

Condition

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

Synonym
partial thickness burns, second degree burns

Health condition

kwaliteit van leven

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Flaminal® Forte, Flammazine®, Partial thickness burns, Wound healing

Outcome measures

Primary outcome

Primary endpoint is time to reach complete re-epithelialization (>95%) in days

of the largest partial thickness burn area (study area), judged by an

experienced burn specialist/ trained researcher.

Secondary outcome

-Clinical outcomes: Need for operation and percentage of TBSA of the study area

that needs operation, colonization rate, infection rate, use of systematic

antibiotics.

-Patients outcomes:

Pain and anxiety: Visual Analogue Thermometer (VAT) and Burn Specific Pain

Anxiety Scale (BSPAS) are used to evaluate pain and anxiety for the treatment.

Health related quality of life (HRQoL): Burn Specific Health Scale (BSHS) -

Dutch and EuroQol -5D questionnaire are evaluated 3, 6 and 12 months post burn

to evaluate HRQoL.

Scarring: Patient and Observer Scar Assessment Score (POSAS), cutometer to

measure scar elasticity and dermaspectometer to assess scar colour are used 3,

6 and 12 month post-burn to evaluate scarring.

-Cost-effectiveness: Medical and non-medical of both treatments are evaluated.

Study description

Background summary

Second degree (partial thickness) burns are painful, difficult to manage and when deeper, have a negative effect on quality of life through scarring, permanent disfigurement and loss of function. Thus, the aim of burn treatment in partial thickness burns is to achieve wound healing, preferably without surgery, as soon as possible to minimize scarring and loss of function of the affected area. The treatment of partial thickness burns should also minimally disturb wound healing by creating an optimum moist wound environment, have debriding and analgesic effect, protect the wound from infection and be convenient for the patient and care takers. However, there is no consensus on the optimal treatment of partial thickness wounds. Flaminal® and Flammazine® are two standard treatment options that provide the above mentioned properties in burn treatment and have good results in the clinical practice. Nevertheless, no randomized controlled study yet compared the effectiveness, cost-effectiveness and quality of life of these two common treatment modalities in partial thickness burns.

Study objective

To evaluate the effectiveness, cost-effectiveness and quality of life of Flaminal® versus Flammazine® in the treatment of superficial and deep partial thickness burns.

Study design

The study is designed as an open label, multi-center, randomized controlled trial (RCT), evaluating the effectiveness, cost-effectivness and quality of life of Flaminal® versus Flammazine® in patients with superficial and deep partial thickness burns.

Intervention

Flaminal® Forte: The treatment with Flaminal® Forte (glucose

oxidase-lactoperoxidase-guaiacol complex in alginogel, FlenPharma) consists of the application of Flaminal® Forte on admittance (within 48 hours of injury). Flaminal® Forte is applied on a non-adhesive dressing. Finally a fixation material is needed to keep the dressing in place. The burn wound is cleaned and rinsed on each dressing change.
Dressing change is performed daily the first three days post-burn and then every two days if desired until they are healed or treated surgically.

Flammazine®: The treatment with Flammazine® (silversulfadiazine 10 mg/g in crème base, Centrafarm Pharmaceuticals) consists of the application of Flammazine® on admittance (within 48 hours of injury). Flammazine® can be applied directly on the wound. The cream layer is covered with a non-adhesive dressing. Finally a net bandage/ dressing is needed to keep the dressing in place. The cream should be re-applied every day till 5 post-burn. Thereafter, the treatment consist of Furacine or Flammazine® on every other day until they are healed or treated surgically.

Study burden and risks

Both treatments are applied in the Netherlands and considered standard treatment. Therefore, there is no additional risk or discomfort for the patient. The measurement and questionnaires during the fellow-up period are performed during the usual out-patient appointments. The main disadvantage for the patient thus is the investment of time.

Contacts

Public
Rode Kruis Ziekenhuis

Vondellaan 13
Beverwijk 1942LE
NL
Scientific
Rode Kruis Ziekenhuis

Vondellaan 13
Beverwijk 1942LE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Competent or temporary incompetent (because of sedation and/ or intubation) patients with partial thickness burns and/ or mixed depth of partial and full thickness burns
- Hospital admission within 48 hour of burn injury
- Written informed consent

Exclusion criteria

- Age < 18 years
- Total body surface area (TBSA) of > 30% (excluding head)
- Burns caused by chemicals, electricity or radiation
- Patients in whom local therapy with a topical agent has already started
- Patients who are expected (according to the responsible medical doctor) to be non-compliant to the study protocol

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:	Recruitment stopped
Start date (anticipated):	03-02-2014
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Flaminal® Forte
Generic name:	Flaminal® Forte
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Flammazine®
Generic name:	Silver sulfadiazine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-06-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-10-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	22-12-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2013-000901-21-NL
CCMO	NL43671.094.13