Flaminal® versus Flammazine® in the treatment of superficial and deep partial thickness burns (Flam study)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27618

Source
NTR

Brief title
Flam study

Health condition

Flammazine®, Flaminal®, wound healing, partial thickness burns

Flammazine®, Flaminal®, wondgenezing, tweedegraads brandwonden

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Dutch Burns Foundation

Intervention

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-6D 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.

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. Eligible patients will be included from Maasstad Hospital - Burn Center (Beverwijk, the Netherlands) and Red Cross Hospital - Burn center (Beverwijk, the Netherlands).

Study objective

The aim of this study is 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

- Complete wound healing (defined as complete re-epithelialization (>95%)). Method: Clinical judgment by two burn specialists. Timepoints: daily, until complete wound healing

- Need for operation and percentage of TBSA of the study area that needs operation. Method: Clinical judgment by two burn specialist in combination with Laser Doppler Imaging (LDI). Timepoints: LDI performed between 48-72 hours after injury. Clinical judgment: between 10-14 post burn day

- Colonization rate and infection. Method: Clinical judgment and swabs taken 2 times a week, until complete wound healing.

- Pain. Method: Visual Analogue Thermometer (VAT), Timepoint: daily until complete wound healing.

- Anxiety. Method: Burn Specific Pain Anxiety Scale (BSPAS), Timepoint: questionnaire is taken 7 ± 2 post burn day.

- Health related quality of life (HRQoL). Method 1: Burn Specific Health Scale (BSHS) - Dutch. Timepoints: Questionnaire is taken on last week of hospitalization and 3, 6 and 12 months post burn. Method 2: EuroQol-6D. Timepoints: Questionnaire is taken on last week of hospitalization and 3, 6 and 12 months post burn.

- Scarring. Methods: Patient and Observer Scar Assessment Score (POSAS), Cutometer to measure scar elasticity and Dermaspectometer to assess scar colour. Timepoints: 3, 6 and 12 month post burn.

- Cost-effectiveness. Method: Medical and non-medical costs until 12 months post burn.

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.

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Eligibility criteria

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 >20%
- 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2014
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-04-2014
Application type:	First submission

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
NTR-new	NL4346
NTR-old	NTR4486
Other	CCMO : CLTMO/13.019/mm

Study results