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

Gepubliceerd: 02-04-2014 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27618

Bron
NTR

Verkorte titel
Flam study

Aandoening

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

Flammazine®, Flaminal®, wondgenezing, tweedegraads brandwonden

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Dutch Burns Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

- 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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Principal investigator
Red Cross Hospital-Burn Center
Postbus 1074

Z.M. Rashaan
Beverwijk 1940 EB
The Netherlands
+31 251 264917

Wetenschappelijk

Principal investigator
Red Cross Hospital-Burn Center
Postbus 1074

Z.M. Rashaan
Beverwijk 1940 EB
The Netherlands
+31 251 264917

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-02-2014
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4346
NTR-old	NTR4486
Ander register	CCMO : CLTMO/13.019/mm

Resultaten