

Functional outcome of the burned hand after skin grafting.

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The hand is one of the most frequent burned body parts. In severely burned hands, surgical wound care is often necessary. A split skin graft is used to cover the wound. Contraction of the skin graft often results in a shortened skin and in the...

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

Samenvatting

ID

NL-OMON23634

Bron

NTR

Aandoening

burns
hands
skin grafting

brandwonden
handen
huidtransplantatie

Ondersteuning

Primaire sponsor: Mrs SJM Sizoo, PT
Maasstad Ziekenhuis
Postbus 9100
3007 AC Rotterdam, tel 010-2913428
Email:sizoos@maasstadziekenhuis.nl

Overige ondersteuning: Stichting Theia, Noordwijk

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the difference in time to complete active full fist position after operation between the index and comparator group, in days.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The hand is one of the most frequent burned body parts. In severely burned hands, surgical wound care is often necessary. A split skin graft is used to cover the wound. Contraction of the skin graft often results in a shortened skin and in the impossibility to make a fist. Burm et al explored the effects of a technique in which hands are grafted in a fist position, with all fingers flexed in a grip position and a flexed wrist. They observed good functional and cosmetic results. However, no quantitative data were reported.

Objective:

1. To assess the feasibility of a new treatment protocol of skin grafting of the burned dorsal hand in fist position with wrist in 30° flexion pre and post op;
2. To explore the effects of skin grafting on the burned dorsal hand in fist position with wrist in 30° flexion, on range of motion, hand function, muscle strength and oedema.

Study design:

A randomised controlled intervention study.

Study population: Patients with burned dorsal hand requiring skin grafting of the dorsal hand and finger(s). A total of 12 hands will be included.

Intervention:

In the index group, the hand will be grafted in a fist position, with all fingers in a fist position and the wrist in 30° flexion. In the comparator group, hand will be grafted in the standard neutral position of wrist and fingers (usual care). In both groups, hands will be fixed 5 days post op in their position.

Main study parameters/endpoints:

The main study parameter is the difference in time to complete active full fist position between the index and comparator group. Secondary outcome assessment include active and passive joint range of motion, observed and self-reported hand function, muscle strength and oedema. Outcome assessors will evaluate functional outcome 7 and 14 days post ok and at 1, 5 and 12 months post ok. Feasibility will be assessed by evaluation of patient inclusion and drop-out and the burden for patients and staff.

Doel van het onderzoek

The hand is one of the most frequent burned body parts. In severely burned hands, surgical wound care is often necessary. A split skin graft is used to cover the wound. Contraction of the skin graft often results in a shortened skin and in the impossibility to make a fist. Burm et al explored the effects of a technique in which hands are grafted in a fist position, with all fingers flexed in a grip position and a flexed wrist. They observed good functional and cosmetic results. However, no quantitative data were reported.

Hand burns which are grafted in a fist position, with all fingers flexed in a grip position and a flexed wrist have an improved functional outcome .

Onderzoeksopzet

Outcome assessors will evaluate functional outcome 7 and 14 days post ok and at 1, 5 and 12 months post ok.

Onderzoeksproduct en/of interventie

In the index group, the hand will be grafted in a fist position, with all fingers in a fist position and the wrist in 30° flexion. Hands will be fixed 5 days post ok in this position.

In the comparator group, hand will be grafted in the standard neutral position of wrist and fingers (usual care). Hands will be fixed 5 days post ok in this position.

Contactpersonen

Publiek

Brandwondencentrum Rotterdam,
Maasstad Ziekenhuis, locatie Zuider
Groene Hilledijk 315
Margriet E. Baar, van
Brandwondencentrum Rotterdam,

Maasstad Ziekenhuis, locatie Zuider
Groene Hilledijk 315
Rotterdam 3075
The Netherlands
+31 (0)10 - 2913428

Wetenschappelijk

Brandwondencentrum Rotterdam,
Maasstad Ziekenhuis, locatie Zuider
Groene Hilledijk 315
Margriet E. Baar, van
Brandwondencentrum Rotterdam,
Maasstad Ziekenhuis, locatie Zuider
Groene Hilledijk 315
Rotterdam 3075
The Netherlands
+31 (0)10 - 2913428

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with burns of the dorsal hand needing skin grafting;
2. The burns should involve at least one of the following joints: Wrist and/or one metacarpophalangeal joint;
3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <18 years;
2. Severe cognitive dysfunction;
3. Poor Dutch proficiency;
4. Co morbidity that can influence wound healing (e.g. diabetes);

5. Pre-injury hand problems;

6. Burns of the palmar hand;

7. Burns involving tendons, muscles and ligaments. Deeper structures should be at length, without arthrogene constraints.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33260

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1901
NTR-old	NTR2017
CCMO	NL28408.101.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33260

Resultaten

Samenvatting resultaten

N/A