A multicenter randomized controlled trial assessing and comparing long-term scar quality after micrografting versus mesh grafting of deep dermal burns

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Our hypothesis is that treatment with micrografting, when compared to conventional meshed graft, will result in a better scar quality and smaller donor site size.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29090

Bron
NTR

Verkorte titel
MvsM

Aandoening

patients with clinically deep burn or deep skin defect between 4% and 20% TBSA

Ondersteuning

Primaire sponsor: University Hospital Ghent, Belgium
Overige ondersteuning: FWO/TBM Grant (2019-2024)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Long-term scar quality 12 months after skin transplantation assessed with the Patient and Observer Scar Assessment Scale (POSAS).

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with deep dermal/subdermal (burn) wounds often have an indication for a skin transplantiation. Most common method is split skin grafting (SSG). Surface area of the skin graft is mostly expanded to retain a small donorsite (wound after harvesting of the skin graft). Skin graft expansion is generally performed by the meshed skin grafting technique, seen this method is considered to be quick and easily applicable. Yet, this technique also has several limiations. For the surgeon this method becomes more cumbersome when the expansion ratio increases. Moreover, the actual expansion of the skin graft is usually lower then the intended expansion ratio and the "fish-net" pattern often stays visible in the eventual scar. An alternative for skin graft expansion is the micrografting technique (Meek technique). In comparision with meshed skin grafting this technique is able to reach large expansion ratio's and thereby maintain small donorsites. As a consequence, this technique is used in particular for very extended (burn) wounds. Both expansion methods are used worldwide in specialized burn centers. Wound healing seams to be similar according to previous published literature. Experience shows an possible advantage of micrografting on scar quality. Three studies compared these two expansion techniques, however none primarily investigated possible differences within long-term scar quality. Given the increasingly prominent role of scar quality in (burn) wound care, a randomized intra-patient controlled trial to compare long-term scar quality of both skin grafting techniques is highly preferred.

Doel van het onderzoek

Our hypothesis is that treatment with micrografting, when compared to conventional meshed graft, will result in a better scar quality and smaller donor site size.

Onderzoeksopzet

During admission, 3 months and 12 months after operation

Onderzoeksproduct en/of interventie

Prior to surgery two comparable (burn) wounds or two equal parts in one (burn) with a minimum size of 36 cm2 will be selected. These wounds will be randomly allocated to the intervention method (micrografting) or the comparison method (meshed skin grafting).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients ≥18 years
• Clinically deep burn or deep skin defect between 4% and 20% TBSA
• Patients with two comparable deep partial thickness and/or full thickness burns, confirmed by laser Doppler imaging (LDI) or deep skin defects, of minimum 1:2 plissee = 36cm², requiring surgery after assessment by a (plastic) surgeon/burn physician
• Patients who are mentally capable to give legal consent or legal representative when the patient is temporarily incompetent (e.g. patient is sedated/ventilated)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patient has participated in another study utilizing an investigational drug or device within the previous 30 days
• Wounds covering face, hands or joints
• Patient has one or more medical condition(s) that in the opinion of the treating physician would make the patient an inappropriate candidate for this study
• Patients who are expected (according to the responsible medical doctor) to be non-compliant to the study protocol. (This includes patients with severe cognitive dysfunction/impairment and severe psychiatric disorders).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8847
Ander register	METC VU medical centre : METC 2020.471.

Resultaten