Frailty assessment In middle aged and elderly patients with burn injuries (FRAIL)

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Frailty causes disability independently of (sub)clinical diseases. Frailty assessment has the potential to improve burn care in middle-aged and elderly patients (≥50 years). If diagnosed in time improvement is possible which enhances both burn care...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29337

Bron
NTR

Verkorte titel
FRAIL

Aandoening

Burns, burn injury

Ondersteuning

Primaire sponsor: NVBZ
Overige ondersteuning: NVBZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess feasibility of three frailty assessment tools in middle-aged and elderly patients with burn injuries; Clinical Frailty Scale, (CFS) Burn Frailty Index (BFI), Groningen Frailty Indicator (GFI).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Frailty is highly prevalent in elderly and is related with an increased risk of falls, disability, hospitalization, and mortality. Frailty assessment has the potential to improve burn care in middle-aged and elderly patients (≥50 years). If diagnosed in time improvement is possible which enhances both burn care treatment and rehabilitation by preventing frailty form worsening if possible. Currently, the frailty risk is assessed in the burn centres in patients aged ≥70 years, by the “Veiligheids Management Systeem Kwetsbare ouderen” (VMS). This is not considered the best fit for burn patients, mainly because not much is known about the use in burn care. Applying frailty assessment tools to an acute elderly population, such as burn patients, is challenging. An assessment tool should be easy to use and trustworthy (valid, feasible and reliable). Several more advanced/better assessment tools are available, like the Clinical Frailty Scale, Frailty Phenotype, Groningen Frailty Indicator and the Burn Frailty Index however, till this day, there is no information regarding their feasibility, validity and reliability on their use in specialized burn care.
Objective: To assess feasibility, validity and reliability of the “Clinical Frailty Scale (CFS)”, the “Groningen Frailty Indicator (GFI)” and the “Burn Frailty Index (BFI)” in the burn population and compare them to two reference standards (“Frailty Phenotype” and “Veiligheids Programma Kwetsbare ouderen”).

Study design: Prospective multicentre cohort study with a 12-month follow-up.
Study population: Middle-aged and elderly patients (≥50 years), with burn injuries, admitted to one of the three Dutch specialised burn centres.

Doel van het onderzoek

Frailty causes disability independently of (sub)clinical diseases. Frailty assessment has the potential to improve burn care in middle-aged and elderly patients (≥50 years). If diagnosed in time improvement is possible which enhances both burn care treatment and rehabilitation by preventing frailty form worsening if possible.

Onderzoeksopzet

Follow up period is 12 months

Onderzoeksproduct en/of interventie

There are no medical interventions involved in the study. The frailty assessment tools consist

of questionnaires and performance-based measures. Data collection at inclusion consists of a short interview of 8 minutes (standard care) and three short questionnaires. Also, two performance tests will be conducted (hand grip strength test and 4.57m (15 feet) walking test – if possible) in the first 72 hours of admission. Together, this takes approximately 30 extra minutes admission, next to the standard care questions. In case patients are not able to complete one or both performance tests, these tests will be replaced by validated questions. Participants are requested to complete a short follow-up questionnaire at discharge and 3- and 12-months post burn. This questionnaire takes approximately 9 minutes to complete. The patient can choose to complete the questionnaire during the regular outpatient visits, to receive it by post, or to answer the questionnaire by phone. The main disadvantage of participation for the patient is thus the investment of time.
The group benefit is mainly the further improvement of tailoring acute care of specialized burn centres to the individual patient.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with a burn injury aged 50 years or more admitted to a burn centre in the Netherlands
- Admission of at least 24 hours
- Informed consent of the patient or legal representative

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Poly-trauma (ISS>16)
- Direct comfort care treatment / expected early mortality <48 hours
- Insufficient knowledge of the Dutch language

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	145
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54400
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9096
CCMO	NL75729.100.20
OMON	NL-OMON54400

Resultaten