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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29337

Source
NTR

Brief title
FRAIL

Health condition

Burns, burn injury

Sponsors and support

Primary sponsor: NVBZ
Source(s) of monetary or material Support: NVBZ

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

To assess predictive validity, construct validity, concurrent validity and discriminative validity of the CFS, BFI and GFI in middle-aged and elderly patients with burn injuries.
To assess reliability of the CFS, BFI and GFI in middle-aged and elderly patients with burn injuries.
To gain insight in the course of frailty over time.

Study description

Background summary

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.

Study objective

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.

Study design

Follow up period is 12 months

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	145
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-11-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54400
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results