Frailty assessment in middle aged and elderly patients with burn injuries, a prospective cohort study (FRAIL)

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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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54400

Source
ToetsingOnline

Brief title
Frailty assessment in middle aged and elderly patients with burn injuries

Condition

- Other condition
- Epidermal and dermal conditions

Synonym
Burn injury, burns

Health condition

brandwonden

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Assessment, Burns, Elderly, Frailty

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

Frailty is highly prevalent in elderly and is related to 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 from worsening if possible. Currently, the frailty risk is assessed in burn centres in patients aged >=70 years, using the *Veiligheids Management Systeem Kwetsbare ouderen* (VMS). It

is unknown whether the VMS is usable in acute burn care. Applying frailty assessment tools to an elderly population in acute care, 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 in specialized burn care.

Study 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 burden and risks

The burden of participation is limited, and associated risks are minimal. 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 and two 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. At discharge they will fill in a short questionnaire (ca 7 minutes). Together, this takes approximately 28 extra minutes on admission. 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 12 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.
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Contacts

Public

Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 of the patient or the legal representative

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	145
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	22-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29337
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75729.100.20
OMON	NL-OMON29337