Cellulitis Severity Score reliability study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41929

Source
ToetsingOnline

Brief title
CSSRS

Condition

- Bacterial infectious disorders
- Skin and subcutaneous tissue disorders

Synonym
cellulitis, erysipelas, skin infection

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cellulitis, realibility, severity

Outcome measures

Primary outcome

Inter-rater variability

Intra-rater variability

Responsiveness

Secondary outcome

none

Study description

Background summary

There are few good outcome measures in clinical cellulitis research. Mortality is low and thus cannot be used, and neither can bacteriological cure, due to cultures often being negative or possibly false positive. Subjective measures such as "cured as decreed by clinician" are unreliable, as a large portion of the patients can have a remaining red and swollen cellulitis laesion, while all bacteria are already dead (at which point treatment is effectively done). At the moment, only redness is being used as primary outcome measure (therapy is said to be effective if there is a cessation of the spread of redness), but this is a derived outcome measure. A numerical outcome measure, such as blood pressure in hypertension treatment, does not exist. For research purposes, it would be useful to have an outcome measure that can tell in both an early and late stage if treatment is effective.

Study objective

Our study will measure several different symptoms/aspects of cellulitis, such as redness, swelling, warmth, pain, fluctuation, ulceration and drainage. Each of these aspects will be scored on a scale of 0-3, adding up to a maximum total score of 21. 10 patients will be evaluated by 3 physicians on 3 timepoints. This allows us to look at inter- and intra-rater variability, and at whether the instrument is able to pick up changes (responsiveness). This is the first step to developing a useful tool in research.

Study design

Patients will be asked in the first 24 hours of their admission in the AMC if they want to participate, and if yes:
- within 3 hours, 3 physicians will evaluate the cellulitis laesion
- 3-12 hours after the first evaluation, 3 more evaluations will take place by the same physicians
- on the 3rd day, 3 more evaluations will take place within 4 hours

Legs with compression bandages will be relieved of their bandages during these time periods.

This gives us 9 scores per patient, which can be compared with eachother to calculate inter- and intra-rater variablity and responsiveness.

Study burden and risks

There should be no risk involved for the patients, but the measuring procedure might be painful for a short duration in some patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged 18 or older
- Admitted with clinical diagnosis of cellulitis (roughly defined as red, warm and indurated skin, with or without pain)

Exclusion criteria

- Cellulitis on other site than arm or leg
- Non-white skin color
- Pre-existent erythematous or edematous (skin)abnormalities at the site of the cellulitis laesion (e.g. dermatitis, lymphedema, deep venous thrombosis sequelae)
- No informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL50352.018.15