

# Cellulitis Severity Score reliability study

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	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 variability 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**

### **Public**

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### **Scientific**

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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