The DANCE study: Duration of ANtibiotic therapy for CEllulitis

Published: 07-01-2014
Last updated: 13-01-2025

To determine if 6 days of antibiotics has equal efficacy compared to 12 days for patients hospitalized with cellulitis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders
Study type	Interventional

Summary

ID

NL-OMON45002

Source
ToetsingOnline

Brief title
DANCE study

Condition

- 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;programma Goed Gebruik Geneesmiddelen

Intervention

Keyword: antibiotics, cellulitis, effectivity, flucloxacillin

Outcome measures

Primary outcome

The primary endpoint is resolution of cellulitis at 14 days after study enrolment, and without recurrence by day 28 (defined as the need for additional antibiotics for cellulitis).

Secondary outcome

Secondary endpoints are length of hospital stay, health-related quality of life, total antibiotic use and effect on direct and indirect health-care associated costs.

Study description

Background summary

Cellulitis is among the most common infections leading to hospitalization, yet the optimal duration of therapy remains ill defined. Pragmatically Dutch guidelines advise 10 to 14 days of antibiotics, which is currently standard of care. Recently it has been shown that antibiotic treatment for pneumonia and urinary tract infections can safely and significantly be shortened. Importantly, in an outpatient setting, treatment of uncomplicated cellulitis with 5 days of antibiotics was as effective as 10 days. We hypothesize that there is no difference in outcomes when patients hospitalized with cellulitis are treated with either a short-course (6 days) or standard-course (12 days) of antibiotics.

Study objective

To determine if 6 days of antibiotics has equal efficacy compared to 12 days for patients hospitalized with cellulitis.

Study design

A randomized, double-blind, placebo-controlled non-inferiority trial.

Intervention

12 days of antibiotic therapy (i.e. flucloxacilline) or 6 days of antibiotic therapy, followed by 6 days of placebo.

Study burden and risks

All participating patients will have to complete four sets of questionnaires (some by phone) and have four extra venous punctures. Also, patients admitted to the AMC will have to undergo a skin biopsy. Possible risks include inferiority of 6 days of antibiotic treatment to 12 days of treatment, i.e. slower recovery of patients in the intervention group. Given positive results of studies in other infectious diseases however, we do not expect this to be the case. The small risk of 6 days being inferior offsets the enormous profits a shortening of therapy for cellulitis would yield.

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

- 18 years of age or older
- Admitted to the hospital for skin infection (cellulitis)
- Capable of giving written informed consent and able to comply with the requirements and restrictions listed in the informed consent form
- Not participating in another clinical therapeutic trial on antibiotics;Healthy volunteers:
- 18 years and older

Exclusion criteria

- Allergy for flucloxacillin, other beta-lactam antibiotics or one of the additives, or flucloxacillin induced hepatitis or liver enzyme disorders.
- Concurrent use of antibiotics for other indications
- Alternative diagnosis accounting for the clinical presentation.
- All cases involving complicating factors (see protocol);Healthy volunteers:
- No abscess, cellulitis, dermatitis or psoriasis in/on the leg in the past 3 months

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2014
Enrollment:	336
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Floxapen
Generic name:	flucloxacilline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	26-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Not approved

Date:	19-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	10-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	13-09-2017
Application type:	Amendment
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

ID: 20276
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-002106-31-NL
CCMO	NL44512.018.13
OMON	NL-OMON20276