Duration of ANtibiotic therapy for CEllulitis (DANCE)

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

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.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20276

Source
Nationaal Trial Register

Brief title
DANCE

Health condition

cellulitis, erysipelas

Sponsors and support

Primary sponsor: Academic Medical Center - University of Amsterdam
Source(s) of monetary or material Support: ZonMw: The Netherlands Organisation for Health Research and Development

Intervention

Outcome measures

Primary outcome

Resolution of cellulitis at 14 days, defined as disappearance of warmth and tenderness at the

site of infection, with substantial improvement in erythema and edema, and without recurrence by day 28, defined as the need of additional antibiotic therapy for cellulitis.

Secondary outcome

- Recurrence of cellulitis by day 90, defined as the need for additional antibiotic therapy for cellulitis

- Objective speed of recovery, measured by improvement in cellulitis severity score (a 7 item scoring system, each with a score between 0-3; items are erythema, warmth, tenderness, edema, ulceration, drainage and fluctuance). Determined at day 1, day 2-3, day 5-6, day 14, and day 28

- Quality of Life scores, using questionnaires Dutch SF-36 and EQ-5D at day 1, day 28, and day 90

- Health care resource utilisation, determined by total antibiotic use and effect on direct and indirect health-care associated costs, using modified versions of iMTA's Productivity Cost Questionnaire (iPCQ) and Medical Consumption Questionnaire (iMCQ). Measured at day 5-6, day 28 and day 90.

- Subjective speed of recovery, using visual Analog Scales (0-10) on pain and on swelling. Determined at day 1, day 2-3, day 5-6, day 14, day 28, and day 90

- Additional antibiotic usage, measuring total usage of additional antibiotics for cellulitis between the end of treatment and day 90.

- Time to relapse; time between end of treatment and the need for additional antibiotics for cellulitis

Additional analyses:
Cellulitis severity score subgroup analysis, to see if the height of the cellulitis severity score influences outcome, using a regression analysis with interaction term for severity score.

Diabetes mellitus subgroup analysis, to see if having diabetes mellitus influences outcome, using a regression analysis with interaction term for diabetes.

Per protocol analysis: like main outcome, but the following will be included: (i) patients with treatment failure, who have received at least 24 hours of study medication, and (ii) patients with treatment success, who have received at least 80% of study medication. Treatment failure is defined as the persistence or progression of signs and symptoms of the acute process after randomization, or the inability to complete the study owing to adverse events. The response is deemed indeterminate when the patients (i) received less than 80% of the study drug for reasons other than treatment failure, (ii) acquired a concomitant infection outside of the skin requiring antibiotic treatment, (iii) were lost to follow-up, or (iv) died

unrelated to the primary diagnosis.

Adjustments for baseline covariates: sensitivity analysis, adjusting the primary outcome for baseline covariates

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 10-14 days of antibiotics, which is the current 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

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 design

Visits scheduled for day 1, day 2-3, day 5-6, day 14, day 28, and day 90.

Intervention

Patients are included on day 1 of their hospital cellulitis episode, and judged on eligiblity for randomization on day 5-6. To qualify for randomization, patients must respond to therapy, defined as absence of fever (temp > 38.0°C) and improvement in cellulitis severity score (see below). Arm 1: Short course (6 days antibiotics, 6 days placebo), experimental Flucloxacillin (1000mg iv OR, later, 500mg capsules), every 6 hours, for 6 days, followed by: Placebo (for flucloxacillin 500mg) 500mg capsules, every 6 hours, for 6 days Arm 2: Standard course (12 days antibiotics), active comparator Flucloxacillin (1000mg iv OR, later, 500mg capsules), every 6 hours, for 6 days, followed by: Flucloxacillin 500mg capsules, every 6 hours, for 6 days

Contacts

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Eligibility criteria

Inclusion criteria

- Admitted to receive intravenous antibiotics for cellulitis/erysipelas
- 18 years of age or older
- Capable of giving written informed consent, able to comply with study requirements and restrictions

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 any of the following complicating factors:
-- Use of antibiotics with Gram-positive activity for more than 4 days in the past 7 days
-- Intensive care unit admission during the last 7 days
-- Severe peripheral arterial disease (Fontaine IV)
-- Severe cellulitis necessitating surgical debridement or fascial biopsy
-- Necrotizing fasciitis
-- Periorbital or perirectal involvement
-- Surgery

-- Life expectancy less than one month
-- Risk factors associated with Gram-negative pathogens as a causative agent:
--- Chronic or macerated infra-malleolar ulcers, or infra-malleolar ulcers with previous antibiotic treatment, in patients with diabetes mellitus.
--- Neutropenia
--- Cirrhosis (Child-Pugh class B or C)
--- Intravenous drug use
--- Human or animal bite
--- Skin laceration acquired in fresh or salt open water
--- Fish fin or bone injuries

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	396
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45002
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4208
NTR-old	NTR4360
ClinicalTrials.gov	NCT02032654
CCMO	NL44512.018.13
OMON	NL-OMON45002

Study results

Summary results
N/A