Duration of ANtibiotic therapy for CEllulitis (DANCE)

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20276

Bron
NTR

Verkorte titel
DANCE

Aandoening

cellulitis, erysipelas

Ondersteuning

Primaire sponsor: Academic Medical Center - University of Amsterdam
Overige ondersteuning: ZonMw: The Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	396
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45002
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A