Pre-hospitale sepsis studie.

No registrations found.

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

Summary

ID

NL-OMON29015

Source
Nationaal Trial Register

Brief title
PRESS

Health condition

sepsis
prehospital
pre-hospital
antibiotics
sepsis
prehospitaal
pre-hospitaal
antibiotica

Sponsors and support

Primary sponsor: Albert Schweitzer hospital
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The reduction of mortality in patients with severe sepsis.

Secondary outcome

1. Prehospital treatment related to the organism, co-morbidity, co-medications, gender, age;

2. Comparison of the intervention group and control group with APACHE/NICE score.

Study description

Background summary

The study is a randomized clinical trial. All ambulances are equiped with lactate scouts. When patients meet the inclusion criteria they will be randomised by particular envelop. The patients in the intervention group, without allergies, will receive augmentin 1,2 gr i.v. within 30 minutes. The controle group will receive no antibiotics. We expect to include 300 patients per year with severe sepsis into our study, devided in two groups. The date of mortality of both groups will be collected and compared when admitted to Albert Schweitzer hospital. The follow up is until discharge or death. The patients who are admitted to the ICU will be compared with the APACHE/NICE score.
Objective of the studie: To give answers to the following questions: 1) Will prehospital treatment with augmentin 1,2 gr v.v.reduce the mortality in patients with severe sepsis? 2) What is the real percentage of septic patients who are suspected to have a severe sepsis in pre hospital phase? 3a) Is there a difference in lactate measurement after prehospital treatment and is it reliable? 3b) Is there a difference in blood cultures taken before and after the augmentin 1,2gr i.v.

Study objective

Prehospital sepsis treatment with antibiotics in severe sepsis reduces mortality.

Study design

Date of enrollment of the first participant 1-11-2012.
The follow up is until discharge or death.

Intervention

The pre-hospital treatment group will receive 1,2 gr augmentin iv. within 30 minutes. The control group will receive no antibiotics. Before giving the augmentin, blood cultures will be taken.

Contacts

Public
Emergency department
Albert Schweitzer hospital
Postbus 444
E. Oskam
Dordrecht 3300 AK
The Netherlands
Scientific
Emergency department
Albert Schweitzer hospital
Postbus 444
E. Oskam
Dordrecht 3300 AK
The Netherlands

Eligibility criteria

Inclusion criteria

1. In the history signs of an infection;

2. Two of the following criteria: - Respitory Rate of > 20/min - Heart rate of > 90/min - A body temperature of > 38 degrees celsius or < 36 degrees celsius;

3. Lactate in veneus blood higher or equal to 2,5 mmol/lt.

Exclusion criteria

1. Allergy for beta-lactam;

2. Age <18 jr.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2012
Enrollment:	2200
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-03-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38203
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3759

Register	ID
NTR-old	NTR3923
CCMO	NL37410.101.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38203

Study results

Summary results

N/A