Pre-hospital treatment of sepsis: reduction in mortality in severe sepsis.

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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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON38203

Source
ToetsingOnline

Brief title
pre-hospital treatment sepsis

Condition

- Bacterial infectious disorders

Synonym
sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: vanuit het ASZ zelf

Intervention

Keyword: antibiotics, prehospital, sepsis

Outcome measures

Primary outcome

The reduction of mortality in patients with severe sepsis.

Secondary outcome

Prehospital treatment related to the organism, co-morbidity, co-medications,

gender, age.

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

Study description

Background summary

Sepsis can be defined as the body's response to an infection. An infection is caused by micro organisms or "germs" (usually bacteria) invading the body, and can be limited to a particular body region (eg, a tooth abscess) or can be widespread in the bloodstream (often called "septicemia" or "blood poisoning"). Sepsis is a medical emergency just like a heart attack or a stroke because there is an interruption of oxygen and nutrients to the tissues including the vital organs such as the brain, intestines, liver, kidneys and lungs.

The surviving sepsis campaign was launched in 2002. In 2004 the surviving sepsis campaign initially produced evidence based guidelines for management of severe sepsis, these were updated in 2008. The primairy goal of the campaign was to reduce the mortality with 25% .
Since in our hospital the implementation of the sepsis criteria all patients with severe sepsis admitted to the ICU were drawn bloodcultures and received antibiotics on the ED.
Robson et al stated in their article the significant contribution of the EMS in treatment of patients with acute coronary syndrome, multiple trauma and stroke. They considered in their article that prehospital staff can improve the outcome of patients with severe sepsis. They concluded that there is a need for further

exploration on this field.
The primary goal of this research is to explore if prehospital antibiotics will reduce mortality in patients with severe sepsis..

Study objective

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 design

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 200 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.

Intervention

The prehospital 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.

Study burden and risks

Because the prehospital treatment of severe sepsis with antibiotics will be the same as in hospital, we will not expect more complications in the study

population.

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

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:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

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

Ethics review

Approved WMO

Date:	05-10-2012
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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: 29015
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37410.101.12
OMON	NL-OMON29015