Het staken van antiobiotica op geleide van een biomarker, procalcitonine bij volwassen patienten opgenomen op de intensive care unit.

Gepubliceerd: 12-06-2009 Laatst bijgewerkt: 13-12-2022

Whether antibiotic guidance by procalcitonin measurements are able to reduce antibiotic usage and duration in Dutch intensive care units.

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

Samenvatting

ID

NL-OMON21923

Bron
Nationaal Trial Register

Verkorte titel
SAPS

Aandoening

Antibiotics/ Antibiotica
Infection/ Infectie
Procalcitonin/ Procalcitonine
Biomarker/ Biomarker

Ondersteuning

Primaire sponsor: not applicable
Overige ondersteuning: VU University medical center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Consumption of antibiotics expressed as the Defined Daily Dosage and duration of antibiotic therapy expressed in days of therapy. In case of multiple antibiotic therapies the therapy that will be used the longest will be scored in duration of therapy;
2. 28-day mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

In all patients antibiotics will be started based on a clinical suspicion of infection or microbiological evidence of an organism. This decision is fully at the discretion of the team and should be made in the same way during the trial as under. Once antibiotics are administered for suspected or proven bacterial infection, a serum sample (T0) will be obtained and patients or their next of kin be asked for informed consent. If informed consent is obtained, the patient will be randomized to the standard therapy arm (control group) or the procalcitonin (intervention) arm. Randomization will be stratified for diagnostic group and centre. If a patient is randomized for the control group, no procalcitonin measurements will be performed. If a patient is randomized for the procalcitonin group, procalcitonin will be measured in the T0-serum sample. On the following days the treating physician will be given daily procalcitonin values until ICU-discharge or until the third day after al systemic antibiotics have been discontinued. Along with daily procalcitonin values the physician will also receive a printed, non-binding advice to consider stopping the prescribed antibiotics if procalcitonin has decreased to 90 % of its peak value measured during this episode or has dropped bellowed the defined values specified in the stopping rules. As for the control group, the physician will receive daily laboratory values as requested and no additional advice.

Doel van het onderzoek

Whether antibiotic guidance by procalcitonin measurements are able to reduce antibiotic usage and duration in Dutch intensive care units.

Onderzoeksopzet

An interim analysis will be performed after enrolment of the first 750 patients.

Onderzoeksproduct en/of interventie

When procalcitonin has reached a peaklevel of above 1,0 ng/ml and the value has decreased to below 0,25 ng/ml, there will be adviced to stop antibiotics (absolute decrease).

A second intervention rule is with a decrease of 90% of the peak value there will also be advised to stop antibiotics (relative decrease).

When the procalcitonin peaklevel is below 1.0 ng/ml, a decrease to below 0.1 ng/ml is needed, before there will be advised to stop antibiotics (absolute decrease).

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Any patient over the age of 18, admitted to the ICU and receiving antibiotics for an assumed infection can be enrolled into this trial. Informed consent has to be obtained in writing from the patient of his/her relatives prior to inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Failure to obtain written consent to participate;

2. Patients receiving prolonged antibiotic therapies (> 3 weeks, e.g. endocarditis);

3. Patients with severe infections due to viruses or parasites;

4. Patients entering the ICU for post-operative observation and/or on antibiotic prophylaxis with an estimated length of stay less then 24 hrs;

5. Patients suffering from plasmodium falciparum malaria, active tuberculosis or cystic fibrosis;

6. Neutropenic patients;

7. Moribund patients.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	2246
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1751
NTR-old	NTR1861
Ander register	VUmc : METC 09/083
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A