Procalcitonine Als marker van Liquor Drain INfecties

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24022

Source
NTR

Brief title
PALADIN

Health condition

drain related meningitis or ventriculitis
drain gerelateerde meningitis of ventriculitis

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfonds Medisch Centrum Haaglanden

Intervention

Outcome measures

Primary outcome

Presence of a bacterial drain infection

Secondary outcome

-Duration of hostpitalization

-Admission of antibiotica

-Drain replacement

-Mortality

-Modified Rankin Scal 3 months after drain placement

Study description

Background summary

This study aims to increase the accuracy of diagnosing a cerebrospinal fluid drain infection. One of the parameters of interest is procalcitonin in cerebrospinal fluid. We will collect some additional cerebrospinal fluid to preserve for testing of other parameters in the future.

Study objective

About 25% of patients who suffer from a subarachnoid hemorrhage or intraventricular hemorrhage have a vital indication for an external ventricular or lumbar drain to aleviate the intracranial pressure. About 5-10% of these patients develop a ventriculitis as a complication of this drain. Diagnosing an infection in this group of patients is difficult because the normal signs of infection (e.g. fever, neck stiffness) are already present due to the blood in the ventricles or for example a systemic infection. The difficulty in interprating the infection parameters leads to a delay in treatment or treatment without a proper indication. This results in increased morbidity as well as prolonged hospitalization, redundant drain replacement and needless antibiotic therapy.
The concentration of procalcitonin in plasma is proven to be an adequate diagnostic tool for diagnosing a systemic bacterial infection. Therefore we hypothesize that intraventricular procalcitonin production is a valuable biomarker for a bacterial drain infection. We will collect some additional cerebrospinal fluid to preserve for testing of other parameters in the future.

Study design

-Baseline

-3 Months

Intervention

The PALADIN study is an observational study. In our hospital daily sampling of cerebrospinal fluid and serum is a routine procedure in patients with a ventricular or lumbar drain. There

will be no additional sampling for this study.

Contacts

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Eligibility criteria

Inclusion criteria

Patients >18 years old with an external lumbar or ventricular drain

Exclusion criteria

Expected death <24 hours

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2014
Enrollment:	250
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4486
NTR-old	NTR4619
CCMO	NL47941.098.14

Study results