Improving the diagnostic tools for spontaneous bacterial peritonitis

Published: 15-06-2006
Last updated: 14-05-2024

The aim of the study is to improve the diagnostic tools of spontaneous bacterial peritonitis.The primary aim is to evaluate the use of dipsticks as bedside diagnostics compared to the current standard polymorphonuclear leukocyte count in identifying...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON29876

Source
ToetsingOnline

Brief title
ID-SBP

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary neoplasms malignant and unspecified

Synonym
infection of ascites, spontaneous bacterial peritonitis

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: Stichting Leveronderzoek (SLO)

Intervention

Keyword: ascites, culture method, diagnostic tools, spontaneous bacterial peritonitis

Outcome measures

Primary outcome

Primary outcome of the study:

- validity of the dipstick

Secondary outcome

Secundary outcomes of the study:

- validity of the culture methods used

- detected micro-organisms

- occurence of bacterial translocation

- development of SBP.

Study description

Background summary

Ascites is in patients with cirrhosis of the liver the most common complication. The occurrence of an infection of ascitic fluid, spontaneous bacterial peritonitis (SBP), is associated with high morbidity and mortality. Early and adequate recognition of the infection makes it possible to start antibiotic treatment at an early stage, thereby preventing associated complications.
The current diagnostic tools have 2 downsides. First, the current standard for determining infection in ascitic fluid is the polymorphonuclear leukocyte count. This is determined in the laboratory and often takes a long time before results become available, especially during after-office hours, causing a delay in treatment. The use of dipstick-tests as bedside diagnostics of SBP can be a good alternative for the rapid detection of infection.
The second shortcoming of the current diagnostics for SBP concerns the culture method. Samples of all diagnostic and therapeutic paracenteses performed are inoculated in blood culture bottles to detect the (possible) presence of a causative micro-organism. In 60% of all ascitic fluid cultures in which an

infection is present, no micro-organism is currently identified. This makes it impossible to adjust the antibiotic treatment for the causative micro-organism.

Study objective

The aim of the study is to improve the diagnostic tools of spontaneous bacterial peritonitis.
The primary aim is to evaluate the use of dipsticks as bedside diagnostics compared to the current standard polymorphonuclear leukocyte count in identifying an infection in ascitic fluid.
The secondary aim is to compare the current standard of ascitic fluid culture, i.e. blood culture bottles, to other different microbiological methods in the detection of micro-organism(s) present.

Study design

single-center prospective study

All patients with cirrhosis of the liver and ascites admitted to the ward of gastroenterology and hepatology of the Erasmus Medical Center and who require either a diagnostic or therapeutic paracentesis are asked to participate in the study.
Ascites of patients who are included in the study will be screened for infection by use of a dipstick test next to the standard polymorphonuclear leukocyte count.
Next to the standard ascitic fluid culture, ascites will undergo different microbiological methods, i.e inoculation of larger volume of ascites, special culture for fungi, for the detection of micro-organisms. In those cases where no micro-organism is identified, a PCR is used to detect bacterial DNA.

Study burden and risks

No extra burden or risk for the patient is associated with this study since samples are obtained during standard treatment procedures. Ascitic fluid is obtained from a paracentesis performed for general treatment. Blood sample is obtained when blood is drawn for general laboratory diagnostics. No extra vena punction is necessary.

Contacts

Public
Stichting Leveronderzoek

Dr Molewaterplein 40

3015 GD Rotterdam
Nederland
Scientific
Stichting Leveronderzoek

Dr Molewaterplein 40
3015 GD Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- cirrhosis of the liver and ascites requiring therapeutic or diagnostic paracentesis
- age > 18 years
- informed consent

Exclusion criteria

-

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2006
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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

No registrations found.

In other registers

Register	ID
CCMO	NL11639.078.06