TIPS with PTFE covered stents vs paracentesis + albumin infusion for the treatment of refractory ascites in patients with cirrhosis: a randomized trial comparing survival, quality of life and nutritional status.

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

Summary

ID

NL-OMON29709

Source
ToetsingOnline

Brief title
TIPS ascites

Condition

- Hepatic and hepatobiliary disorders

Synonym
refractory ascites

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Gore Inc.

Intervention

Keyword: decompensated cirrhosis, paracentese, refractory ascites, TIPS

Outcome measures

Primary outcome

Define survival at one year in patients with liver cirrhosis, complicated by ascites, which is not well controlled by paracentesis, treated by TIPS versus paracentesis with albumin infusion.

Secondary outcome

Evaluate the differences between the two treatment options concerning:

· Quality of life

· Nutritional status

· Development of other portal hypertension related complications (digestive bleeding, hepatorenal syndrome, SBP, hepatic encephalopathy)

Study description

Background summary

For patients with liver cirrhosis, complicated by ascites, which is not well controlled by paracentesis (surgical puncture of the abdominal cavity for the aspiration of peritoneal fluid), because ascites returns quickly, there is an alternative, TIPS-procedure. For this procedure, a small tube (a stent) is placed between two veins in the liver to decompress the veins of the liver. When this is successful, ascites will decrease as well. However, the main drawback of TIPS, which, until recently, occurred in most cases (80%) was the

closure of the tube. Because of this the pressure in the veins of the liver increased again, and the ascites returned as well.
This problem of TIPS, however, now seems solved, because of recent improvements in stent-technology. TIPS procedures are nowadays being carried out using covered stent-grafts instead of open bare metal stents, and this has dramatically improved the patency of the stents, and thus decreases the possibility of the development of ascites. The absence of ascites might improve nutritional status, because there is no fluid in the abdomen, which could bother the appetite and quality of life.
When ascites could be treated earlier, this could lead to better nutritional pattern and hence decreases the possibility of complications and thus improves survival. This has never been investigated with the current stents.

Study objective

The aim of this study is to compare the new covered TIPS-stent with paracentesis with albumin infusion with regard to nutritional status, quality of life and survival.
The theory is that when ascites is treated in an earlier stage of liver cirrhosis, patients will keep a better nutritional status. Hence, the risk of complications because of weakness could be decreased and thus quality of life and survival improved.

Study design

In total 136 patients, divided over 7 hospitals in Europe, will take part in this study. The study was started from a hospital in Toulouse, France and the Erasmus medical center is the only Dutch center participating.
To determine whether one treatment option is better than the other, the participants will be randomized into two groups. Whether TIPS is more effective than the common used therapy, paracentesis with albumin infusion, can be discovered by comparing the groups. The participants will be controlled every three months for one year, from the moment the TIPS-stent is placed, or the first paracentesis has taken place. Several measurements will be done. After the last measurement after 12 months the study will end.
The study will continue for 3 years, 2 years in which patients will be asked to participate, and one year to follow the last participants.

Intervention

TIPS (Transjugular Intrahepatic Portosystemic Shunt) procedure.

Through a vein in the neck, a small tube (a stent) is placed between two veins in the liver to decompress the veins of the liver.

Study burden and risks

TIPS-procedure:

TIPS will be performed under general anesthesia. Nausea and vomiting after waking are less frequent with the current medication techniques, but might occur. During the first hours after anesthesia some problems concerning memory or concentration might arise.
Because of intubating (to ensure the respiration during the intervention)dental damage by the tube could arise. Unforeseen complications, which are life threatening, like a grave allergy, cardiac arrest, or respiration arrest are very rare, and they occur in less than 3 out of 10.000 anesthesia*s. The stent will be placed between the veins in the liver through a vein in the neck. The place in the neck where this is done might get a bruise after the intervention. Some days after the intervention pain from the veins may be perceived. This will disappear spontaneously. Other complications that might occur after the TIPS-procedure, are temporal cardiac arrhythmias, jaundice and fever. In rare cases puncture of the liver capsule with the needle can occur and blood might flow into the abdominal cavity, but usely this has no major consequences.
TIPS increases the risk of hepatic encephalopathy. This is confusion and dullness related to the liver disease. When this happens it might be neccesary to close the stent, to decline the disturbances. Patients who will be treated with TIPS will be hospitalized to place the stent; this will take some days.
When the patient does not get better after the TIPS-procedure, he will be treated further by the conventional therapy, paracentesis with albumin infusion.

Participation in the study means that the patient will be controlled 5 times during 1 year in view of the study. In many cases this will go together with the usual control in the policlinic. During these controls several measurements will be done. Twice abdominal ultrasonography will be done, twice radiological examination will be done to determine nutritional status and every control a questionnaire should be filled in and blood will be taken.

Burden and risks of conventional therapy (paracentesis with albumin infusion):
During the year patient will undergo this treatment, every time there is a big amount of ascites.

Both treatment groups get a low-salt diet and will be controlled in the policlinic every three months. In all controls participants will be weighed, particular measurements will be done, a questionnaire should be filled in and blood and urine is taken for specific measurings. In the first and in the last visit nutritional status will be observed by x-ray on the radiology-department (by measuring the fat content of the body). After 6 months and 1 year an abdominal ultrasonography will be done.

Within the framework of the study the patient has to visit the hospital 5 times extra. These controls will as much as possible be subsequent to the controls of the treating doctor, but will take approximately 30 minutes extra each visit.

When ultrasonography or nutritional-status-examination at the radiology-department is done the visit will take a couple of hours longer.

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

patients of both sexes, age > 18 and < 70 years with cirrhosis and refractory or recurrent ascites, who signed the informed consent form

Exclusion criteria

Child Pugh Score > 12

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2007
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2007
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
Other	ISRTCN58150114
CCMO	NL13196.078.06