Multicenter randomized trial comparing short-term stenting versus balloon dilatation for dominant strictures in primary sclerosing cholangitis

Published: 01-02-2011
Last updated: 04-05-2024

The primary objective of the study is to compare the efficacy of single session balloon dilatation with short-term stent placement in PSC patients with a worsening of their cholestatic complaints.

Ethical review	-
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON38315

Source
ToetsingOnline

Brief title
Dilstent 2

Condition

- Hepatic and hepatobiliary disorders

Synonym
inflammation of the bile ducts, Primary Sclerosing Cholangitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: balloon dilatation, Dominant biliary strictures, Primary Sclerosing Cholangitis, short-term stenting

Outcome measures

Primary outcome

The main outcome of the study is the difference in re-intervention free

survival time between both groups.

Secondary outcome

The comparison between both groups of efficacy with regard to the improvement

of cholestatic symptoms, biochemical cholestasis, and quality of life.

To compare the safety of a single balloon dilatation session with short-term

stenting.

Study description

Background summary

Titel: Multicenter randomized trial comparing short-term stenting versus balloon dilatation for dominant strictures in primary sclerosing cholangitis.

Primary sclerosing cholangitis is a chronic progressive inflammatory disease of the biliary tree leading to liver cirrhosis. During it's course, dominant bile duct strictures occur in approximately 50% of patients. These can be accompanied by worsening of cholestatic symptoms and jaudice and are an indication for endoscopic treatment. The best form of treatment, either balloon dilatation or short-term stent placement, has never been formally investigated.

Study objective

The primary objective of the study is to compare the efficacy of single session balloon dilatation with short-term stent placement in PSC patients with a

worsening of their cholestatic complaints.

Study design

This is a multicenter, open-label, randomized, intervention study with a medical device.

Intervention

During ERCP half of the subjects will receive a stent to treat the dominant stricture and the other half will have the stricture strechted out with a dilating balloon.

Study burden and risks

Currently both interventions belong to standard patient care armamentarium. The burden for the patient consists of slightly more visits during the two year follow-up (every 3 months instead of every 4-6 months) in addition to which blood will be collected more often. During these visits the patient will also be asked to fill in a quality of life questionnaire and a PSC symptom questionnaire.
ERCP is associated with a low mortality (<0.5%) and acceptable morbidity (5%). Most dreaded complications are severe post-ERCP pancreatitis (<2%) and suppurative cholangitis (<2%). From the available retrospective literature data the incidence of these complications does not seem to differ between the two treatment modalities.

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

PSC
18-75 years
progression cholestatic complaints
elevated total bilirubin and alkaline phosphatase

Exclusion criteria

advanced PSC
suppurative cholangitis
malignancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2011
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	biliary stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01398917

Register	ID
CCMO	NL34454.018.10