Clinical investigation of the safety of ALIMAXX-B biliary stent for bile duct obstruction

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The primary objective of the study is to demonstrate safety and efficacy of the ALIMAXX-B* covered biliary stent.The secondary objective of the study is to evaluate technical success of stent placement, , re-interventions and time to occlusion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON35349

Source
ToetsingOnline

Brief title
ALIMAXX-B* safety

Condition

- Gastrointestinal stenosis and obstruction

Synonym
CBD obstruction, malignant CBD obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Merit Medical Systems
Source(s) of monetary or material Support: Merit Medical Systems;Inc

Intervention

Keyword: biliary obstruction, safety, stent

Outcome measures

Primary outcome

The Primary endpoints of this trial will be as follows:

a. Device safety, including assessments of stent related complications and overall complication rate comparable to clinical literature

Secondary outcome

The secundary outcomes of the studie are as follows:

a. Reduction in conjugated bilirubin >30% or return to normal range compared to baseline value at 1 week post stent placement.

b. Independent review of cholangiographic and X-ray images confirming stent patency and position

c. Assessment of stent position at all follow-up visits via X-ray

d. Assessment of biliary re-intervention; defined as any endoscopic, percutaneous or surgical procedure to improve biliary drainage post stent placement.

e. Assessment of patient survival post stent placement

f. Occurrence of unanticipated adverse device effects (UADE) or serious adverse device effects (SADE)

g. Assesment of clinically significant stent occlusion or migration within 6 month follow-up or prior to death, whichever occurs first. Clinically significant stent occlusion will be suggested by the development of symptoms including pruritis and/or cholangitis. Signs suggesting clinically significant

occlusion include development of jaundice. Findings suggesting clinically significant stent occlusion include a 30% increase in bilirubin from its lowest point following stent placement. Migration of the stent by > 0.5 cm in association with any of the above defined Symptoms, Signs or Findings will be interpreted as clinically significant. These observations and/or additional findings of cholestasis (elevation of ALP, AST and ALT) with or without imaging defining ductal dilation may be interpreted to define clinically significant stent occlusion

Study description

Background summary

The majority of patients who have malignant biliary strictures cannot undergo resection. Biliary stent placement is a well-established, palliative treatment for patients with malignant biliary strictures. Plastic stents can effectively palliate malignant biliary obstruction. However, a common complication of plastic stents is late stent occlusion, therefore, necessitating stent replacement.
The larger diameter self-expanding metal stents (SEMS) not only reduce stent occlusion but also significantly increase stent patency.
This is a clinical evaluation of ALIMAXX-B*, a fully covered SEMS, which will be conducted outside of the US. The ALIMAXX-B* used in this study is CE marked and meets the regulatory requirements of the countries where clinical sites reside.

Study objective

The primary objective of the study is to demonstrate safety and efficacy of the ALIMAXX-B* covered biliary stent.
The secondary objective of the study is to evaluate technical success of stent placement, , re-interventions and time to occlusion.

Study design

Prospective, multi-center, single arm, open-label, confirmatory study compared

to clinical literature.

Intervention

An ALIMAXX-B biliary stent will be placed during ERCP.

Study burden and risks

The study schedule exist of an enrollment visit and 3 follow up visits.
During the enrollment visit patients will be ask about their medical history and their use of medication.
After that a blood sample will be taken to measure liver function tests (comparable with standard treatment). Additional the stent will be placed during ERCP.
After 1 week, 3 weeks and 6 months their will be a follow up visit. Patients will be ask about their medication use and another blood sample will be taken to measure liver function tests. After that a supine X-ray will be taken to determine the position of the stent.
Patient will be followed for a maximum of 6 months.

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

a. Malignant obstructive disease at the level of the extrahepatic CBD
b. Willing and able to comply with study procedures and provide written informed consent
c. > 18 years of age presenting with biliary obstruction

Exclusion criteria

a. Benign obstruction of the CBD
b. Malignancy involving intrahepatic ducts or duodenum
c. Stricture >8cm in length
d. Prior bilairy metal stent
e Perforation of any duct within the biliary tree
f. Life expectancy of <90 days
g. Disease that is amenable to curative resection
h. INR > 1.5
i. Prior gastric bypass or biliroth type I or type II gastric resection

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):	04-12-2009

Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	ALIMAXX-B covered biliary stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25336.041.08