Evaluation of the Effectiveness of Evolution® Biliary Stent System * Fully Covered (study number 10-014)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41734

Source
ToetsingOnline

Brief title
EBFC (10-014)

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
Biliary duct obstruction or Biliary duct blockage

Research involving
Human

Sponsors and support

Primary sponsor: Wilson-Cook
Source(s) of monetary or material Support: Cook Medical;regional sponsor William Cook

Europe

Intervention

Keyword: Biliary, Fully Covered, Stent

Outcome measures

Primary outcome

The objective of this study is to evaluate the effectiveness of the Evolution® Biliary Stent System * Fully Covered when used in palliation of malignant neoplasms in the biliary tree (e.g., when used to treat patients with obstruction of the biliary tree caused by malignant neoplasm). The primary endpoint will be 1-month total serum bilirubin * 3.0 mg/dL and freedom from symptomatic recurrent biliary obstruction requiring reintervention within a period of six months or until death, whichever comes first.

Secondary outcome

The secondary objectives are to evaluate the performance of the Evolution® Biliary Stent System * Fully Covered. These secondary endpoint measures were chosen because of their clinical relevance and because they will provide insights to physicians and the sponsor about the performance of the Evolution® Biliary Stent System * Fully Covered.

The secondary endpoints are as follows:

* Technical success at treatment (see Appendix C, Definitions).

* Successful attempts to remove a stent during initial stenting procedure if needed.

* Successful attempts to reposition a stent during initial stenting procedure if needed.

* Acute procedural success (see Appendix C, Definitions).

* Clinical success over time (see Appendix C, Definitions).

* Assessment over time in individual symptoms associated with biliary obstruction compared to baseline for each patient.

* Assessment in blood bilirubin levels at 1 month compared to baseline for each patient (absolute and percent decrease).

* Time to symptomatic recurrent biliary obstruction requiring reintervention.

* Adverse events.

* Stent migration (Stent migration, full: A stent that has moved from its original location such that no portion of the stent remains within the study lesion. Stent migration, partial: A stent that has moved from its original location such that a portion of the stent remains within the study lesion).

Study description

Background summary

Advances in biliary stent design maintain the goals of providing adequate drainage and ameliorating patient symptoms while minimizing the need for reinterventions and thus improving the overall quality of life in patients with unresectable malignant biliary obstruction. This study will add to the current body of knowledge by evaluating the effectiveness of the Evolution® Biliary Stent System * Fully Covered when used in palliation of obstruction caused by malignant neoplasms in the biliary tree.

This study will to collect safety and effectiveness data for the Evolution® Biliary Stent System * Fully Covered when used to treat strictures/occlusions that are caused by malignant neoplasms.

Study objective

The study will collect data related to symptoms of recurrent biliary stent obstruction requiring reintervention, adverse events, and a variety of important secondary endpoints including technical success and time to symptomatic recurrent biliary obstruction requiring reintervention.

Study design

This study is designed as a prospective, multicenter, single-arm study involving up to 15 investigative sites. This study will be conducted in compliance with global regulations and standards as applicable (e.g., investigational in the U.S., post-market in the European Union).

Data will be captured pre-procedure, during the procedure, and blood tests at 1 month after the procedure. Monthly telephone follow-ups at 1-6, 9, and 12 months will also occur after the procedure. The patient will be requested to provide information regarding adverse events since the last follow-up, clinical symptoms of biliary obstruction, and any adjunctive tumor reduction therapy during the monthly calls. If the clinical symptoms reported by a patient are considered by the physician to indicate possible obstruction of the stent, a visit to the clinic for further assessment and blood tests will be obtained to confirm biliary obstruction.

Patients will exit the study after any of the following:
* Completion of scheduled clinical and telephone evaluations to 12-month follow-up,
* Patient dies,
* Patient withdrawal lost to follow-up,
* Demonstrates symptoms of recurrent biliary obstruction requiring reintervention, even if not treated,
* Surgical removal of the stent due to reasons other than biliary obstruction (e.g., excessive pain),
* Closure of the study.

Intervention

Placement of a Evolution® Biliary Stent System * Fully Covered stent for palliation of malignant neoplasms in the biliary tree (i.e., when used to treat patients with obstruction of the biliary tree caused by malignant neoplasm).

Study burden and risks

This clinical study does not involve any additional risk beyond those associated with biliary stenting. Of note, all participating patients may also be concurrently receiving cancer treatments, such as chemo- or radiotherapy, as part of their standard of care. Tumor shrinkage associated with these therapies may increase the risk for stent migration compared to results

reported in earlier studies when patients with concurrent chemo- or radiotherapy were not included.
The IFU identifies the following risks:
Potential complications associated with ERCP including, but not limited to:
* Pancreatitis
* Cholangitis
* Cholecystitis
* Cholestasis
* Aspiration
* Perforation
* Hemorrhage
* Infection
* Sepsis
* Allergic reaction to contrast or medication
* Hypotension
* Respiratory depression
* Respiratory arrest
* Cardiac arrhythmia
* Cardiac arrest

Additional complications that can occur in conjunction with biliary stent placement include, but are not limited to:
* Trauma to the biliary tract or duodenum
* Perforation
* Obstruction of the pancreatic duct
* Stent migration
* Stent occlusion
* Ingrowth due to tumor or excessive hyperplastic tissue
* Tumor overgrowth
* Stent misplacement
* Pain
* Fever
* Nausea
* Vomiting
* Inflammation
* Recurrent obstructive jaundice
* Bile duct ulceration
* Death (other than due to normal disease progression)

The lists above provide potential adverse events associated with a common interventional method of treating the disease (ERCP) and events specific to biliary duct stenting. Risks of events associated with the natural course of biliary malignancy are not included in the above list, and are not expected to be any greater if the patient is enrolled in this study.

Methods to Minimize Risks

Risks are mitigated by including only investigators with experience in biliary stenting in this clinical study. Patients will be selected according to the labeled indication and in accordance with inclusion/exclusion criteria outlined in this document. In addition, adverse event information and clinical signs/symptoms of biliary obstruction are collected through regular follow-up (i.e., at 1, 2, 3, 4, 5, 6, 9, and 12 months).
The device design, non-clinical testing, clinical study design, and manufacturer*s IFU are intended to minimize the risks associated with the use of this device. The risks of the study have been minimized and the potential benefits outweigh the risks in light of the importance of the knowledge to be gained about the performance of the Evolution® Biliary Stent System * Fully Covered. The capture, handling, and storage of the study data are done in compliance with applicable regulations to minimize the risk of release of any personal health information.

Contacts

Public
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Scientific
Wilson-Cook

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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 patient is deemed suitable for inclusion in the study if the patient meets the following criteria:
1) The patient has an inoperable malignant neoplasm causing biliary obstruction or stricture.
2) The patient is a candidate for placement of a palliative fully covered metal stent.

Exclusion criteria

A patient will be excluded from the study if any of the following are true:
1) Patient age is less than 18 years.
2) Patient is unwilling or unable to sign and date the informed consent.
3) Patient is unwilling or unable to comply with the follow-up schedule.
4) Patient has undergone (within 30 days prior to enrollment) or is planning to undergo brachytherapy with transpapillary or percutaneous implantation of intracavitary radiation sources.
5) Patient is simultaneously participating in another investigational drug or investigational device study in which the patient has not completed the follow-up phase for the primary endpoint at least 30 days prior to enrollment in this study.
Note: Patients receiving approved, nonexperimental adjuvant therapy for malignancies may participate in this study. This includes treatment protocols with drugs or treatments approved for use in the country where the study is being conducted. The patient will not be permitted to enroll if also participating in a clinical study of an investigational drug, device, or treatment (e.g., clinical study of a drug, device, or treatment not already cleared for use in the country where the study is being conducted) unless the patient is at least 30 days past the primary endpoint prior to enrollment in this study. Note: Enrollment of a patient in another investigational drug or investigational device study during participation in this study will be considered a protocol deviation.
6) Patient has current anatomy upstream of intended stent placement compromising the flow of bile from the liver such that stent placement may not alleviate the biliary obstruction symptoms (e.g., very small intrahepatic ducts).
7) Patient for whom endoscopic procedures (including ERCP) are contraindicated.
8) Patient with presence of a metal biliary stent.
Note: Patients who have occluded plastic biliary stents (i.e., total serum bilirubin >3.0 mg/dL removed prior to the introduction of the study stent may be included in the study.
9) Patient with presence of any esophageal or duodenal stent.
10) Patient with known hypersensitivity/allergy or contraindication to any component of the stent, delivery system, or medication required to complete the procedure (e.g., contrast), which, in the investigator*s opinion, cannot be adequately premedicated.
11) Patient with coagulopathy.
12) Patient with diffuse intrahepatic metastases that involve greater than 10% of the liver.
13) Patient with a short life expectancy inappropriate for treatment with a metal stent (i.e., < 3 months).

14) Patient is pregnant.
15) Patient has an active alcohol or substance abuse issue.
16) Patient has jaundice secondary to a cause other than biliary duct obstruction (e.g., active hepatitis, cirrhosis).
17) Patient has a baseline total serum bilirubin * 3.0 mg/dL.;Endoscopically Confirmed
Exclusion Criteria
A patient will be excluded from the study if any of the following are true:
1) Patient with inoperable malignant neoplasm causing biliary obstruction or stricture located less than 2 cm downstream from the hepatic bifurcation.
2) Patient with stricture(s) that cannot be adequately dilated, if necessary, to allow passage of the wire guide or stent through the obstructed area.
3) Patient with perforation of any duct within the biliary tree or the GI tract.
4) Patient with concurrent bile duct stones that could not be removed prior to implantation of the study stent.
5) Patient with stricture(s) greater than 6 cm in total length (i.e., more than one stent is needed).

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):	11-03-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Evolution® Biliary Controlled - release stent fully covered
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2015
Application type:	Amendment
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
ClinicalTrials.gov	NCT02046096
CCMO	NL48621.078.14