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Prospective study to assess the success rate and safety of placing novel lumen apposing stents (LAMS) in the bile duct to relieve jaundice

Submission date
09/05/2018

Recruitment status
No longer recruiting

Registration date
16/05/2018

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Endoscopic retrograde cholangio-pancreatography (ERCP) is an endoscopic procedure done with the help of X-rays and is the conventional mode of draining obstructed bile ducts. However, it is successful in 80% of the patients. Hence, one in five patients require alternative means of drainage. An alternative way is to do a drain through the skin under X-ray guidance (Percutaneous trans-hepatic cholangiogram (PTC). This procedure has good success rate but is associated with high mortality rate of 23% and serious harmful event rate of 35%. This is the current standard of care for patients who have a failed ERCP.
EUS-BD (Endoscopic ultrasound-guided biliary drainage) is an endoscopic procedure where the bile duct is identified under EUS (Endoscopic ultrasound) guidance in the first part of small bowel and a stent (a splint placed temporarily inside a duct to relieve an obstruction) is deployed in between the bile duct and small bowel. The chance of a serious harmful event rate associated with this procedure is around 10-15%. This is a new procedure and there are few studies which reported similar serious harmful event rate. A new lumen apposing metal stent (LAMS) is available on the market and we surmise that it will have even less serious harmful event rate compared to PTC. This has not been proved except for a small retrospective study. Hence, we propose a prospective observational study to assess the safety and effectiveness of these stents. This study aims to evaluate the safety and effectiveness of a new stent in the drainage of cancerous obstruction of common bile duct. Obstructive Jaundice secondary to cancerous distal bile duct strictures are often difficult to treat and patients are profoundly jaundiced. This prevents treatments such as chemotherapy as they can develop liver failure if they receive chemotherapy when they are jaundiced. Delay in treatment of cancer often has harmful results to the patient. Hence, facilitating drainage of the bile duct and relieving jaundice is an important step in the management of patient.

Who can participate?
Adults aged 18 – 90 years with malignant (cancerous) common bile duct obstruction

What does the study involve?
Participants undergo the endoscopic ultrasound-guided biliary drainage procedure, using liumen-

apposing stents. Following this, they remain in hospital overnight, and then they are followed up at 7 days and 30 days for data collection and to assess harmful events and 30 day mortality.

What are the possible benefits and risks of participating?
The intended clinical benefits are we may be able to establish bile duct drainage. This will relieve jaundice and improve symptoms such as reduced appetite, lethargy and itching. As obstructive jaundice is one of the contraindications for chemotherapy this treatment may help participants access chemotherapy earlier. Participants are invited to an event at the end of the study to explain the results. The results will be published through a scientific journal as an original article which may help us to improve the treatment of such patients with obstructive jaundice.
The anticipated risks associated with this procedure are infection, abdominal pain, bleeding, bile leak, leakage of air in to the peritoneum when we deploy the stent, stent migration in to the bowel, perforation (hole in the adjacent bowel or other organs) and death. However, the risk of these complications may be lower with EUS guided biliary drainage. The risk of death is 23 % with PTC in the first 30 days after the procedure. We anticipate that the risk of death may be significantly reduced with EUS guided biliary drainage. An official medical review reported that the risk procedure related death was 0.5%. However, this study did not report the 30 day mortality. The procedure is done by experienced endoscopists who are trained in the above procedure. They are trained in identifying these complications and deliver the necessary treatment if required.

Where is the study run from?
1. Nottingham Digestive Diseases Centre (UK)
2. NIHR Nottingham Biomedical Research Centre (UK)

When is the study starting and how long is it expected to run for?
November 2017 to April 2020

Who is funding the study?
1. Nottingham Digestive Diseases Centre (UK)
2. NIHR Nottingham Biomedical Research Centre (UK)

Who is the main contact?
Dr Suresh Vasan Venkatachalapathy (Public)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
237130

ClinicalTrials.gov number

Secondary identifying numbers
18GA021, IRAS 237130

Study information

Scientific Title
Proof of Concept Study: Safety and Feasibility Study of Lumen-Apposing Stents (LAMS) in EUS-Guided Biliary Drainage

Acronym
EUS-BD

Study objectives
A new single-stage procedure using a novel lumen apposing metal stent is now available for use and it may have less adverse events compared to PTC. Hence, we propose a prospective observational feasibility study to assess the safety and success of this new method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - approval pending, ref: 237130

Study design
Prospective feasibility study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Malignant common bile duct obstruction

Interventions

This is a prospective feasibility study to assess the safety and efficacy of EUS- guided biliary drainage. All adult participants who have inoperable distal malignant CBD stricture and failed ERCP have the opportunity to be recruited to the study. Participants are identified through the regional hepatico-pancreato-biliary regional multi-disciplinary (HPB MDT) meetings. Their CT/ MRI scan, EUS reports and cytology if available are reviewed in the HPB MDM and only upon confirmation that they have inoperable cancer, they are recruited to the study. Participants are considered for ERCP in the first instance, as usual standard of care, but if they fail to establish biliary drainage using ERCP they are eligible for recruitment into the study.
Participants are enrolled and a baseline visit is performed. All information about the study is provided to the participants . They are given 24 hours to make an informed decision about participating in the study. These participants are ill with jaundice and if they do not wish to participate in the study then we facilitate alternative mode of biliary drainage as soon as possible. Hence, we give them 24 hours to decide if they want to participate in the study.
After the procedure is performed, participants are followed for 30 days (Day 1, 7 and 30). Two follow-up appointments are performed to assess adverse events and concomitant medications. After the day 30 visit is completed, the subject has completed the study. Information collected at each protocol required visit is documented below:
1. Baseline Visit
a. Informed Consent
b. Inclusion / Exclusion Criteria
c. Demographics
d. Medical History
e. Concomitant medications
f. Investigations including quality of life (QoL: SF 50) liver function test (LFT), urea and electrolytes UE), full blood count (FBC) and clotting screen.

2. EUS- BD Procedure
a. EUS landmarks identified.
b. Bile duct identified and measured (mm).
c. Distance between the bile duct and duodenum measured (mm).
d. If < 8mm- then the LAMS stent will be deployed under EUS guidance.
e. Data including patient tolerability, technical success of the procedure and immediate complications will be collected.

3. Immediate Post Procedure Evaluation (Clinic visit)
a. Participants stay overnight and are reviewed by the endoscopist or another consultant gastroenterologist the following day.
b. Data including complications liver function test (LFT), urea and electrolytes UE), full blood count (FBC) and clotting screen is collected.
c. Participants are discharged if they are well.

4. Day 7 Follow-up Clinic visit
Data including complications, QoL, liver function test (LFT), urea and electrolytes UE), full blood count (FBC) and clotting screen is collected.

5. Day 30 Follow-up Clinic visit.
Data including complications, QoL liver function test (LFT), urea and electrolytes UE), full blood count (FBC) and clotting screen is collected.

6. Unscheduled Visit, as applicable (Clinic visit)
Participants have the contact details of the BRU research nurses who informs the chief investigator if there are any complications.

7. End of Study
End of study is reached after completion of the Day 30 visit.

During the study the following data is collected
1.Patient demographics
2. Technical success of the procedure
3. Immediate complications (<7 days)
4. Delayed complications (7-30 days)
5. 30-day mortality

Intervention Type
Device

Primary outcome measure
The safety and technical success of placing lumen apposing stents (LAMS) in the drainage of bile duct is assessed by reviewing the endoscopy report, patient notes, blood tests and patient interviews on day 1, 7 and 30 post procedure

Secondary outcome measures
1. Clinical success (i.e. improvement or resolution of jaundice) is assessed using blood tests and patient interviews on day 1, 7 and 3 following EUS guided biliary drainage
2. Procedure-related complications are measured reviewing the endoscopy report, patient notes, blood tests and patient interviews on day 1, 7 and 30 post procedure following EUS guided biliary drainage
3. 30-day mortality is recorded from hospital records following EUS guided biliary drainage
4. Quality of life is measured using patient interviews following EUS guided biliary drainage

Overall study start date
01/11/2017

Completion date
01/04/2020

Eligibility

Key inclusion criteria
1. Adult patients aged 18-90 years
2. Distal malignant CBD stricture and failed ERCP drainage secondary to either altered ampullary anatomy, difficult cannulation, duodenal infiltration or obstruction at the level of D1/D2 junction

3. Common bile duct (CBD) should at least be dilated to 14mm in diameter (it would not be technically feasible to deploy the stent with diameters less than 15mm)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Participants suitable for curative pancreatic or bile duct resection (participants are reviewed in HPB MDM for this and then recruited if they are considered inoperable)
2. All participants who have proximal malignant BD (ie; with in 1cm from the hilum or involving the hilum) strictures and those with distal CBD stricture with duodenal stent in situ occluding access via D
3. Participants are not deemed fit enough to undergo endoscopic drainage, either at ERCP or EUS-BD
4. Distance between bile duct and duodenum lumen >8mm

Date of first enrolment
01/07/2018

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham Digestive Diseases Centre (NDDC)
Queen’s Medical Centre campus,
Derby Road,
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NG2 7UH.

Study participating centre
NIHR Nottingham Biomedical Research Centre (BRC)
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nottingham Digestive Diseases Centre (NDDC) and NIHR Nottingham Biomedical Research Centre (BRC)

Results and Publications

Publication and dissemination plan
Upon completion of the study, the data will be analysed and a final report will be submitted. The results of the study will be disseminated through national and international conferences and as an original article in a relevant journal. We will notify the participants of the outcome of the study via either as a presentation or provision of the final publication. The participant can specifically request the results of the study to their respective PI upon completion of the final study report. The study protocol and the full study report will be made publically available upon completion of the study.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	02/03/2022	Yes	No