EUS-guided gallbladder drainage with the AXIOS stent in patients with acute cholecystitis unsuitable for surgery: a feasibility study.

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To determine the safety and feasibility of EUS-guided gallbladder drainage with the AXIOS stent in patients with acute cholecystitis unsuitable or at high risk for surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON37861

Source
ToetsingOnline

Brief title
GALAXY

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
cholecystitis, gallbladder inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Xlumena Inc, Mountain View, California, USA

Intervention

Keyword: cholecystitis, drainage, EUS, stent

Outcome measures

Primary outcome

- Short term major complications, defined as any stent-related life threatening and/or severe event during stent placement or within week (7 days), e.g. bile leakage with development of bile peritonitis, significant bleeding, unscheduled endoscopic/surgical intervention due to adverse event.

- Long term major complications, defined as any stent-related life threatening and/or severe event during occurring later than 1 week (7 days) from stent placement.

- Recurrence of cholecystitis; defined as recurrence of acute cholecystitis according to Tokyo Guidelines after complete clinical response, either before or after stent removal.

Secondary outcome

- Technical success of stent placement; defined as transmural passage of the stent across the stomach or duodenum into the gallbladder.

- Functional success of stent placement; defined as normalization of clinical parameters of acute cholecystitis within 96 hours. Clinical parameters reported are abdominal pain evaluated by the patients on a 10-point visual analogue scale, temperature, white blood cell count and serum C-reactive protein concentration.

- Total procedure time; time between first entry of and last withdrawal from the mouth.

- Technical success of stent removal; defined as removal of the stent in a single session without complications.

- Stent patency at stent removal; defined as a patent stent opening assessed during upper endoscopy.

- Stent migration at stent removal: defined as any migration of the AXIOS stent into the gallbladder (distal migration) or the stomach or duodenum (proximal migration).

- Gallbladder characteristics including the presence of gallstones at 12 months after initial stent placement.

Study description

Background summary

In elderly patients or patients with significant comorbidity, urgent cholecystectomy in case of acute cholecystitis carries a high risk of morbidity and mortality. To date, percutaneous gallbladder drainage is the treatment of choice in these high risk patients. Recently, the technique of EUS-guided transmural drainage has been described for drainage of the gallbladder with a novel self-expandable metal stent (AXIOS stent), specially designed for transmural drainage. Technical and functional results of this new technique have been found to be promising, without serious complications.

Study objective

To determine the safety and feasibility of EUS-guided gallbladder drainage with the AXIOS stent in patients with acute cholecystitis unsuitable or at high risk for surgery.

Study design

This is a multi-center prospective non-randomised open label feasibility study

in 30 patients.

Intervention

EUS-guided transgastric or transduodenal gallbladder drainage with placement of an AXIOS stent (Xlumena Inc., Mountain View, California USA). No comparator is used.

Study burden and risks

The benefit of EUS-guided gallbladder drainage includes less patient discomfort associated with an external drain, required for percutaneous gallbladder drainage. Besides, complications due to inadvertent tube removal will be reduced.

The burden of study participation for the patient consists of undergoing EUS-guided gallbladder drainage instead of percutaneous gallbladder drainage. Before the procedure and the first 96 hours after the procedure, the patient will be asked to score the intensity of their abdominal pain. Measurement of temperature and taking blood samples to determine white blood cell count and serum C-reactive protein concentration will be conducted as part of standard care. After three months endoscopy will be performed and the stent will be removed if there are no stones present. If there are stones present, an additional endoscopy will be performed after one month. Patients will be contacted by phone up to six times in a period of a year to obtain information about signs and symptoms of recurrence of acute cholecystitis and other possible complications taking approximately 5-10 minutes for each phone call. One year after the initial stent placement transabdominal ultrasound will be performed.

The risk associated with participation is development of pneumoperitoneum (9.0%), bile leakage (2.9%) and stent migration (1.5%). The complication rate might be slightly higher with this new technique. However, the most prevalent complication, pneumoperitoneum, can be considered as a minor complication which can be managed conservatively in most patients.

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

- Acute cholecystitis, defined according to Tokyo Guidelines:
A. Local signs of inflammation: (1) Murphy*s sign, (2) RUQ mass/pain/tenderness
B. Systemic signs of inflammation: (1) Fever, (2) elevated CRP, (3) elevated WBC count
C. Imaging findings: imaging findings characteristic of acute cholecystitis
Definite diagnosis: (1) One item in A and one item in B are positive
(2) C confirms the diagnosis when acute cholecystitis is suspected
clinically
- Unsuitable for surgery, due to one (or more) of the following items:
A. ASA score > II (ASA = American Society of Anesthesiology)
B. APACHE II score >= 12 (APACHE = Acute Physiology and Chronic Health Evaluation)
C. Onset of symptoms >=7 days before first presentation in hospital
D. Advanced malignancy
E. Unsuitable for surgery upon expert*s opinion for any other reason
- >=18 years
- Eligible for endoscopic intervention
- Written informed consent

Exclusion criteria

- Pregnancy

- Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study
- Patients unwilling to undergo follow-up assessments
- Patients diagnosed with pancreatitis (defined as elevated serum amylase more than three times the upper limit of normal)
- Altered anatomy of the upper gastrointestinal tract due to surgery of the esophagus, stomach and duodenum
- Patients with liver cirrhosis, portal hypertension and/or gastric varices
- Abnormal coagulation: INR > 1.5 and not correctable and/or platelets < 50.000/mm3
- Previous drainage of the galbladder

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):	21-09-2012
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	AXIOS stent;lumen apposing stent
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	08-06-2012
Application type:	First submission

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	NL39924.041.12