Een onderzoek naar de veiligheid en mogelijkheden van het plaatsen van een stent in de galblaas tijdens echo-endoscopie bij patiënten met een acute galblaasontsteking die niet in aanmerking komen voor een operatie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24539

Source
Nationaal Trial Register

Brief title
GALAXY

Health condition

cholecystitis, EUS-guided drainage, SEMS, stent

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Xlumena Inc., Mountain View, California USA

Intervention

Outcome measures

Primary outcome

1. 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;

2. 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;

3. 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

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

2. 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;

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

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

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

6. 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);

7. 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. Our objective is 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 objective

N/A

Study design

1. First 96 hours after the procedure: abdominal pain on a 10-point visual analogue scale, daily measurement of temperature, white blood cell count and serum C-reactive protein concentration;

2. 1 week follow up for complications;

3. 3 month: endoscopy, only if possible regarding medical condition of patient, with removal of stent;

4. 3-monthly follow up until one year after placement;

5. 1 year: addominal ultrasound.

Intervention

EUS-guided transgastric or transduodenal gallbladder drainage with placement of an AXIOS stent.

Contacts

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Eligibility criteria

Inclusion criteria

1. 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;

2. 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.

3. ≥18 years;

4. Eligible for endoscopic intervention;

5. Written informed consent.

Exclusion criteria

1. Pregnancy;

2. Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study;

3. Patients unwilling to undergo follow-up assessments;

4. Patients diagnosed with pancreatitis (defined as elevated serum amylase more than three times the upper limit of normal);

5. Altered anatomy of the upper gastrointestinal tract due to surgery of the esophagus, stomach and duodenum;

6. Patients with liver cirrhosis, portal hypertension and/or gastric varices;

7. Abnormal coagulation: INR > 1.5 and not correctable and/or platelets < 50.000/mm3;

8. Previous drainage of the galbladder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-06-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-09-2012
Application type:	First submission

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
NTR-new	NL3340
NTR-old	NTR3633
Other	UMCU : 12-116/E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A