Veiligheid en effectiviteit van een nieuwe 'big-cup partially covered' stent als palliatieve behandeling van een kwaadaardige maaguitgangsobstructie.

No registrations found.

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

Summary

ID

NL-OMON28005

Source
Nationaal Trial Register

Brief title
CUBIC

Health condition

malignant gastric outlet obstruction, stent placement, enteral stent, cholangiocarcinoma, duodenal cancer, gastric cancer, pancreatic cancer

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Stent patency.

Secondary outcome

1. Technical success defined as successful placement and deployment of the stent across the stricture;

2. Clinical success defined as relief of symptoms compatible with GOO and/or an improvement of the GOOSS-score 1 week after stent placement;

3. Improvement of the GOOSS-score during total follow-up;

4. Procedure (for example perforation, bleeding and sepsis) and stent-related (for example stent migration, stent occlusion by tumor ingrowth, late onset perforation) complications including 30-day mortality;

5. Quality of life score (EORTC QLQ-C30 (version 3) combined with EQ-5D including the EQ-VAS);

6. WHO performance status;

7. Procedure-related hospitalization time (days);

8. Time until regain of oral intake (days);

9. Survival (days).

Study description

Background summary

N/A

Study objective

Placement of this stent will achieve good technical and clinical success rates, that are at least comparable to previously reported results of studies with other stent-designs. Moreover a low re-obstruction rate is expected due to the new stent design. This subsequently may cause a low number of re-interventions and a prolongation of clinical success. In addition this may also be reflected in relatively high quality of life (QoL)-scores.

Study design

Baseline, 1 week, 2 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months.

Intervention

Endoscopic placement of a new partially covered big-cup stent in the duodenum for palliative treatment of malignant gastric outlet obstruction.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histological proven malignancy of the periduodenal area;

2. GOOSS-score of 0 (no oral intake), 1 (liquids only) or 2 (soft solids) (see table 1) and/or suffering from nausea or vomiting or early satiety;

3. Age of at least 18 years;

4. Informed consent.

Exclusion criteria

1. Potentially curable disease;

2. Obstruction of the proximal stomach;

3. Pre-procedural evidence for additional strictures in the small bowel or colon;

4. Previous treatment with a self-expanding metal stent for the same condition;

5. Unable to undergo upper gastrointestinal endoscopy;

6. Unable to fill out quality of life questionnaires.

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):	01-08-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2012
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	NL3384
NTR-old	NTR3555
Other	METC AMC : W12_120
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A