

Surgery versus stent for malignant gastro-duodenal obstruction

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR531; 945-06-503

Study information

Scientific Title

Surgical gastrojejunostomy or endoscopic duodenal stent placement for the palliation of malignant gastric outlet obstruction: a randomised study

Acronym

SUSTENT study

Study objectives

To compare a surgical procedure (gastrojejunostomy [GJJ]) with endoscopical stent placement in patients with malignant gastric outlet obstruction (GOO).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised multicentre active-controlled parallel-group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gastric outlet obstruction (GOO)

Interventions

1. Duodenal stent placement
2. Gastrojejunostomy

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Total area under the survival curve, adjusted for the ability to eat at least soft solids (GOOSS score of 2 or more).

Key secondary outcome(s)

1. Procedure-related (within 7 days) and long term (later than 7 days) minor and major complications
2. Reinterventions or recurrent obstructions
3. Survival, calculated from day of randomisation
4. Health related quality of life, including the perceived burden of the procedure, burden of reintervention and generic and disease specific HRQoL
5. Cost and cost-effectiveness

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Obstructive cancer (more than 25% of the circumference as seen by endoscopy) extending from the distal duodenum
2. Gastric outlet obstruction scoring system (GOOSS) score of 0 (no oral intake) or 1 (liquids only)
3. Incurable or metastatic disease
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Evidence of other strictures in the gastrointestinal (GI) tract
2. Previous gastric, periampullary or duodenal surgery
3. Previous (palliative) treatment for the same condition
4. World Health Organization (WHO) performance score of 4 (patient is 100% of time in bed)
5. Unable to fill out quality of life questionnaires

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010		Yes	No
Results article	results on cost effectiveness	01/05/2010		Yes	No

Protocol article	protocol	14/10/2006	Yes	No
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