ISRCTN06702358 https://doi.org/10.1186/ISRCTN06702358

Surgery versus stent for malignant gastro-duodenal obstruction

Submission date	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2010	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
150

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)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam
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3000 CA

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	14/10/2006		Yes	No
Results article	results	01/03/2010		Yes	No
Results article	results on cost effectiveness	01/05/2010		Yes	No