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Traditional open, open fAst track recovery and laParoscopic fASt track multimodal management for surgical patients with colon carcinomas: TAPAS study

Submission date 13/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/07/2009	**Overall study status** Completed	
Last Edited 10/08/2010	**Condition category** Cancer	

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
N/A

Study information

Scientific Title
A prospective cohort study to investigate cost-minimisation of Traditional open, open fAst track recovery and laParoscopic fASt track multimodal management for surgical patients with colon carcinomas: TAPAS study

Acronym
TAPAS study

Study objectives
The TAPAS study is likely to indicate the treatment programme which is most cost minimising in the participating hospitals. Together with the evidence on equality of long term clinical effectiveness (from literature), it will justify or reject hospital investments on fast track and/or laparoscopic programmes. Dissemination of the outcome to other hospitals may have a major impact on medical expense nationwide.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC commission EZ Tilburg approved on the 13th January 2007 (ref: 0665)

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colon carcinoma/colorectal surgery

Interventions
Cohort 1: Conventional open surgery is the control exposure
Cohort 2: Open surgery with fast track recovery
Cohort 3: Laparoscopic surgery with fast track recovery

Three separate time periods are used in order to prevent attrition bias. Before each new cohort starts a quality control will be carried out by the expert project advisors from the research group on fast track recovery and laparoscopic surgery. The overall follow-up is 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Costs (direct medical and indirect non-medical). Analysed for the in hospital period and time back to work.

Secondary outcome measures
1. Mortality
2. Post-operative morbidity
3. Complications (early complications less than 30 days post-operative; late complications 30 - 52 days post-operative)
4. Surgical-oncological resection margins
5. Hospital stay
6. Time back to recovery/work
7. Cosmesis
9. Pain and health status
10. Quality of life

All outcome measures and in particular quality of life is measured pre-operation and at 6, 12 and 52 weeks post-operation.

Overall study start date
01/01/2007

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Male or female patients with malignant disease of the colon with indication to elective surgical resection
2. Aged 18 years or older
3. Reasonable to good health (American Society of Anaesthesiologists [ASA] grade I or II)
4. No known relevant allergies
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3 x 15 x 5 = 225 participants

Key exclusion criteria
1. Pregnancy
2. Aged under 18 years
3. Moderate to severe systemic disease (ASA III and higher)
4. History of previous upper abdominal surgery
5. History of previous abdominal surgery
6. Psychiatric disease or inability to assess follow up (e.g. lack of knowledge of the Dutch language)

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Dunantstraat 10
Tilburg
Netherlands
5017 KD

Sponsor information

Organisation
St Elisabeth Hospital (St Elisabeth Ziekenhuis) (Netherlands)

Sponsor details
Hilvarenbeekseweg 60
Tilburg
Netherlands
5022 GC

Sponsor type
Hospital/treatment centre

Website
http://www.elisabeth.nl/

ROR
https://ror.org/04gpfvy81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Elisabeth Hospital (St Elisabeth Ziekenhuis) (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?
Results article	results	14/06/2010		Yes	No