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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Jurrian Reurings

Contact details

Dunantstraat 10 Tilburg Netherlands 5017 KD j.reurings@elisabeth.nl

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

 $3 \times 15 \times 5 = 225$ 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