

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/08/2010	Condition category Cancer	<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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/04gpfvy81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Elisabeth Hospital (St Elisabeth Ziekenhuis) (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	14/06/2010		Yes	No