Stepped implementation of Enhanced Recovery After Surgery in major gynaecological surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22049

Source
NTR

Brief title
SINERGY

Health condition

Perioperative care; elective abdominal surgery, gynaecological oncology

Perioperatieve zorg, electieve abdominale chirurgie, gynaecologische oncologie

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)
Source(s) of monetary or material Support: Zon-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

The primary outcome is length of postoperative hospital stay.

Secondary outcome

Additional outcome measures will be length of recovery, guideline adherence and implementation costs. An effect, economic, and process evaluation will be conducted throughout the trial.

Study description

Background summary

The Enhanced Recovery After Surgery (ERAS) programme is an evidence-based perioperative management programme that aims at an early recovery after major surgical trauma and consequently at a reduced length of hospitalisation. The ERAS programme proved to be safe and is already standard care in colorectal surgery for many years. This study focuses on large scale implementation of the ERAS programme in major gynaecological surgery in the Netherlands.

Study objective

To implement the Enhanced Recovery After Surgery (ERAS) programme in elective gynaecological surgery on large scale in an (cost) effective manner is challenging. The traditional used breakthrough method for health care improvement on large scale showed at the best moderately positive effects and requires considerable investments in professional time and energy. The objective of this study is to compare the breakthrough programme with a new stepped approach designed to deliver an optimal effect of implementation efforts at the lowest possible costs.. It is hypothesised that the stepped implementation strategy is more effective compared to the traditional breakthrough methodology for the nationwide uptake of evidence based best practice.

Study design

- Retrospective baseline measurement

- Prospective monitoring of patient characteristics, process indicators and outcome measures during the one year implementation period.

- Evaluation of the effectiveness of both strategies every three months after every step or teaching session and at the end of the project. The timing of the teaching sessions of the breakthrough project will be synchronously with the timing of implementation steps.

Intervention

The intervention group receives an innovative stepped implementation strategy comprising four levels of intensity of support. Implementation starts with generic low-cost activities and builds up to the highest level of tailored and labour-intensive activities. The decision for a stepwise increase in intensive support will be based on the success of implementation so far.

In the control arm hospitals receive the traditional breakthrough strategy with educational sessions and the use of plan-do-study-act cycles for planning and executing local improvement activities.

Contacts

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Eligibility criteria

Inclusion criteria

All Dutch hospitals that are authorised in 2013 to perform major abdominal surgery in gynaecologic oncology patients are eligible for inclusion.

Exclusion criteria

The hospitals that are already participating in a structured and documented local perioperative improvement programme will be excluded from this study to avoid interference between programmes.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-07-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3896
NTR-old	NTR4058
Other	ZonMW : 837003002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A