Fast track surgery versus conventional recovery strategies for colorectal surgery (Protocol)

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[Intervention Protocol]

Fast track surgery versus conventional recovery strategies for colorectal surgery

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate beneficial and harmful effects of fast track recovery after surgery for colorectal carcinomas and benign conditions, by investigating whether "fast track" recovery after colorectal resections differs in primary (hospital stay and severe complications) and secondary (mortality, quality of life, minor complications, need for re-operation) outcome measures in reference to conventional recovery. If present, other outcome measures, such as cost-effectiveness, time to return to work, postoperative need for analgesia etc will also be investigated.

BACKGROUND

Description of the condition

Colorectal carcinoma is one of the cancers with the highest incidence in the world and surgery is the main treatment modality (Weitz 2005). Besides malignancy, other benign condition such as diverticulitis often require surgery. Surgical approach may be the conventional open procedure or an laparoscopic resection. Complication rates for patients having resections, either open or laparoscopic, are reported as high as 15% and 20% respectively (Basse 2005). The length of hospital stay varies between 10 and 15 days, for both laparoscopic and open surgical procedures. Main reasons for increasing length of clinical postoperative treatment are pain, nausea and persistent ileus (Basse 2000; Basse 2002; Anderson 2003; Kehlet 2003; Basse 2004).

Description of the intervention

In recent years, a trend towards new peri-operative treatment strategies has been developed; "Fast track surgery" or Enhanced Recovery After Surgery (ERAS). Fast track surgery programs focus on a number of techniques that facilitate early recovery after major surgery by preserving pre-operative bodily composition and organ functions. Techniques include epidural or local anaesthesia, minimally invasive techniques, optimal pain control and aggressive postoperative rehabilitation (Wilmore 2001) The first to incorporate these strategies in elective colonic surgery were Kehlet and associates in the mid 90's, showing a reduction of days to recovery

to as early as 3 days postoperatively (Kehlet 2007).

How the intervention might work

By reducing stress and pain in colorectal resections, together with aggressive postoperative mobilisation and early oral feeding, the body's stress response is reduced and organ dysfunction is reduced to a minimum, thus facilitating early recovery and reducing postoperative morbidity and mortality.

Why it is important to do this review

The implementation of fast track programs in colorectal surgery is supported by review of controlled trials (Wind 2006) and randomised controlled trials (Khoo 2007). However, the effect of separate interventions is not known. Also, several studies have shown the implementation of fast track protocols in colorectal surgery to be slow. Therefore, better evidence and information on the effects and possible dangers of fast track programs in colorectal surgery may well lead to increased implementation around the world with major implications, both for patients, organisation of health care and economical cost (Kehlet 2008).

OBJECTIVES

To evaluate beneficial and harmful effects of fast track recovery after surgery for colorectal carcinomas and benign conditions, by investigating whether "fast track" recovery after colorectal resections differs in primary (hospital stay and severe complications) and secondary (mortality, quality of life, minor complications, need for re-operation) outcome measures in reference to conventional recovery. If present, other outcome measures, such as cost-effectiveness, time to return to work, postoperative need for analgesia etc will also be investigated.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised clinical trials comparing any type of fast track recovery strategy for resections in colorectal disease to conventional recovery strategies.
Trials will be included irrespectively of blinding, number of patients randomised, and language of the article.
Should the amount of data be insufficient, i.e. no or a very limited number (<3) of RCT's available, quasi randomised studies will be included. Non-randomised controlled trials will be mentioned but not considered for inclusion in this review.

Types of participants

Patients with indications for surgical treatment of colorectal carcinoma will be included. Both laparoscopic and open surgical techniques are eligible for inclusion. The patients with colon and rectal carcinoma will be analyzed separately if possible. In case data is scarce on one type of patients or in case no distinction is made in the results of the trials between both groups, then all trials will be considered in one comparison and subgroup analysis will be performed if appropriate.

Types of interventions

In this review we will compare any type of "fast track" recovery strategy after colorectal resections with the conventional recouperation. Both laparoscopic and open surgical techniques are aligible for inclusion. Fast track recovery strategies include programs using epidural or local anaesthesia, minimally invasive techniques, optimal pain control and aggressive postoperative rehabilitation to achieve early recovery after colorectal surgery. An important problem to also be investigated is the quality of ERAS protocols used in studies. detailed review of literature suggests that not all studies review acutal ERAS protocols, but rather conventional care that has been protocolised.

Types of outcome measures

Primary outcome measures are considered those to be reasons for conducting a trial and usually are main decisional factors for choosing between operative techniques. When primary outcome measures are not different, then secondary outcome measures become important as reasons for choosing a treatment.

Primary outcomes

The primary outcome parameters in this review will be:
Lenght of hospital stay
Major complications: including abdominal sepsis, signs of anastomosic leakage, need for reoperation, persistant ileus, intra-abdominal abscesses, bleeding, leakage, burst abdomen (Platzbauch), late incisional hernia and adhesions.
Other parameters related to hospital stay, such as bowel function and tolerance of early normal diet will also be investigated.

Secondary outcomes

Secondary outcome measures are all other outcomes assessed in comparing the conventional postoperative protocol with fast track protocols.
These include operative time, hospital stay, minor complications, quality of life. As a secondary outcome measure, mortality (both early and late), with early mortality defined as death within 30 days will be analysed. If data is present, differences in other secondary outcomes like analgesic use, postoperative pain, costs and differences between modaltiy of surgery will be considered as well. Minor complications include; pneumonias, wound infections, deep vein thrombosis, and urinary tract infections.

Search methods for identification of studies

The devised search string will be entered in the following databases:
-The Cochrane Database of Systematic Reviews,
-Database of Abstracts of Reviews of Effects (DARE),
-The Cochrane Central Register of Controlled Trials (CENTRAL),
-Health Technology Assessment (HTA) Database,
-NHS Economic Evaluation Database, all in The Cochrane Library (***Issue 3, 2008***),
-MEDLINE (1985 untill present),
-EMBASE (1985 untill present) and
-ISI Web of Knowledge (Web of Science) (1985 untill present)
-Webcasts of the annual meetings of the American Society of Colon and Rectal Surgeons (ASCRS)
Our aim is to perform a maximal sensitive search in order to perform a more complete review. Our search strategy has been developed in accordance to the guidelines outlined in the Cochrane Handbook for Systematic Reviews of Interventions, chapter 5.2. The last part of this strategy, concerning the sensitive search for randomised and controlled trials, corresponds to the Cochrane Highly Sensitive Search Strategy for Identifying Reports of Randomised Controlled Trials phases 1, 2 & 3. We started the search from the year 1985 given that 'fast track´ approaches were not described before 1989 and therefore it would be very unlikely that any relevant trials will be found prior to this year. However, if any relevant studies are to be identified in the years 1987 or 1988 the search will be expanded to start from 1980.

Electronic searches

The specific search strategies that are formed are adapted to the syntax and capacities of each database. The used implementations of our search strategy for the different databases are shown in Table 1.

Searching other resources

Additional relevant trials by cross-reference checking will be looked for in the reference lists of identified randomised trials. Finally, all authors of included trials will be requested by letter for additional information on any published, unpublished, or ongoing trials.

Data collection and analysis

The review will be conducted according to the present protocol and the recommendations by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008).

Selection of studies

The titles, abstracts and descriptor terms of all downloaded material from the electronic searches will be read by WRS and irrelevant reports will be discarded. All citations identified will then be inspected independently by WRS and by JCR to establish relevance of the article according to the pre-specified criteria. If any uncertainty arises about the relevance of the study, the full article will be obtained. Studies will be reviewed for relevance based on study design, types of participants, types of interventions and outcome measures.
After identifying relevant articles, WRS and JCR will independently apply the inclusion criteria. Differences will be resolved by discussion with a third reviewer, CL, and reaching a consensus among all reviewers. All identified trials will be listed in the characteristics of included studies table and an evaluation whether the trials fulfil the inclusion criteria will be made. Excluded trials and the reasons for exclusion will be listed as well (characteristics of excluded studies).

Data extraction and management

Inclusion and exclusion criteria in each trial. In case of randomised trails the following data on the randomisation procedure will be extracted:
(1) Number of randomised patients
(2) Number of patients not randomised and reasons for non-randomisation
(3) Exclusion after randomisation
(4) Drop-outs
(5) 'Intention-to-treat' analysis.
In case of observational studies the data needed to perform the quality assessment will be extracted. Also information on sample size, mono- or multicenter study design, primary and secondary outcome measures, use of antibiotic prophylaxis, surgical experience, use of diverting ileostomy, performing of anal mucosectomy and configuration of constructed pouch will be registered. In

RCT's the general descriptive data (like gender, age, body mass index (BMI), and American Society of Anaesthesiology (ASA) classification) are supposed to be equally divided due to randomisation. Therefore statistical analysis of patient characteristics in RCT's is not appropriate (Assmann 2000). However, comparability of groups considering these general descriptive data will be important if quasi-randomized or cohort studies are to be included and therefore the comparability of groups considering these general descriptive data will be checked and presented in an additional table.

If during data extraction it turns out that essential data or information on methods are missing from certain trials/studies, the authors of those trials or studies will be contacted and asked to provide for the missing data. Extracted data will be stored and managed using the review manager software package RevMan, version 5.0.5, provided by The Cochrane Collaboration.

Assessment of risk of bias in included studies

In this review both randomised controlled trials (RCTs) and non-randomised controlled trials (non-RCTs) may be included. For both types a different assessment method was chosen.

Assessment of methodological quality of randomised clinical trials

Based on the available empirical evidence (Schultz 1995; Moher 1998; Kjaergard 2001; Higgins 2008) the methodological quality of RCTs will be assessed using the following items.

Generation of the allocation sequence

Adequate, if the allocation sequence was generated by a computer or random number table. Drawing of lots, tossing of a coin, shuffling of cards, or throwing dice was considered as adequate if a person who was not otherwise involved in the recruitment of participants performed the procedure.

Unclear, if the trial was described as randomised, but the method used for generation of the allocation sequence was not described.

Inadequate, if a system involving dates, names, or admittance numbers was used for the allocation of patients.

Allocation concealment

Adequate, if the allocation of patients involved a central independent unit, on-site locked computer, or sealed envelopes.

Unclear, if the trial was described as randomised, but the method used to conceal the allocation was not described.

Inadequate, if the allocation sequence was known to the investigators who assigned participants or if the study was quasi-randomised.

Blinding

Adequate, if the trial was described (at least) as blind to participants or assessors and the method of blinding was described. We are well aware that it is very difficult to properly blind trials comparing surgical treatments, therefore one level of blinding was considered adequate.

Unclear, if the trial was described as (double) blind, but the method of blinding was not described.

Not performed, if the trial was not blinded.

Follow-up

Adequate, if the numbers and reasons for dropouts and withdrawals in all intervention groups were described or if it was specified that there were no dropouts or withdrawals.

Unclear, if the report gave the impression that there had been no dropouts or withdrawals, but this was not specifically stated.

Inadequate, if the number or reasons for dropouts and withdrawals were not described.

Assessment of methodological quality of non-randomised clinical trials

Quality assessment for non-randomised clinical trials is a complex topic and is generally considered to be an area of ongoing research. In an extensive review of this topic (Deeks 2003, chapter 4) investigators reviewed 193 tools for quality assessment in literature, and concluded that based on quality and design of these tools only 6 tools were suitable for use in systematic reviews. They also concluded that all 6 tools needed some type of modification before being fully suitable for that purpose.

In this review we will use a modification of the Methodological Index for Non-Randomised Studies (MINORS) (Slim 2003). This tool is one of the few validated and tested methods specifically developed for the assessment of quality of non-randomised trials. To adhere to the guidelines of the Cochrane Handbook, the following modifications were applied:

· Four of the 12 items of the MINORS were disregarded in the quality assessment, because these items related to the applicability, reporting quality, and precision of the results, rather than the validity of the assessed trials (Higgins 2008, section 6.7.2).

· Every item was used independently to distinguish between high and low quality trials, rather than using the sum score of this list. The draw-backs of using summary scores are the decreased transparency to readers of the review and the evidence showing that different scales could results in contradicting results when applied in the same review (Jüni 1999).

The modified MINORS list is outlined in Table 2. Every study will be assessed using this method by WRS and JCR independently. Discrepancies will be solved by consensus discussion with a third reviewer, CVL, if necessary.

Measures of treatment effect

With adequate data available statistical analysis of binary data will be conducted using relative risks (RR) as the summary statistic. Trials with zero events in both arms are to be excluded from meta-analyses. However, a sensitivity analysis using risk differences (RD) can be performed with inclusion of these trials, and in case of inconsistency the results of this sensitivity analysis reported.

For continuous outcomes weighted mean differences (WMD) were used as the summary statistic. Authors, however, often pre-

sented their results in medians with ranges due to suspicion of skewed data, while means with their standard deviations (SD) are needed for meta-analysis. Authors then will be contacted for additional data if necessary. Additionally, sensitivity analyses imputing data for missing means and standard deviations (calculated from available medians and ranges) are to be performed (Hozo 2005)

Dealing with missing data

In analysis of data, missing of data is of importance. In case of missing data we will investigate whether this data is missing at random, in which case the missing data will not be regarded as being of influence on outcome, or data missing not at random, in which case missing data will have to be obtained. We will contact authors, requesting the missing data. When this is insufficient, we will impute missing data with replacement values, and treating these as if they were observed (e.g. last observation carried forward, imputing an assumed outcome such as assuming all were poor outcomes, imputing the mean, imputing based on predicted values from a regression analysis), accounting for uncertainty of the data.

Assessment of heterogeneity

Both the random-effects model (Dersimonian 1986) and the fixed-effect model (Demets 1987) for pooling effect estimates will be explored.

In case of no discrepancy (and no heterogeneity) the fixed-effect models will be presented.

In case of discrepancy between the two models (eg, one giving a significant intervention effect and the other no significant intervention effect) both results will be reported. Discrepancy will only occur when substantial heterogeneity is present.

Most weight will be put on the results of the fixed-effect model if the meta-analysis includes one or more large trials, provided that they have adequate methodology. (By large trials we mean trials that outnumber the rest of the included trials in terms of numbers of outcomes and participants (eg, more than half of all included events and participants)).

Otherwise, most weight will be put on the results of the random-effects model as it incorporates heterogeneity. The reason for this is that the random-effects model increases the weight of small trials. Small trials however are more often than large trials conducted with unclear or inadequate methods (Kjaergard 2001).

Finally, in situations of excessive heterogeneity we will refrain from reporting a pooled estimate when inappropriate.

The main focus of looking at heterogeneity in meta-analysis is to discriminate true effect modifiers from other sources of heterogeneity. Heterogeneity will be calculated by the Cochrane Q test and quantified by measuring I2. If excessive heterogeneity is detected, data will be re-checked first and then adjusted. Extreme outliers will be excluded (and tested in sensitivity analyses) when adequate reasons are available. If excessive heterogeneity still remains, depending on the specific research question, alternative methods will be considered: subgroup analysis and meta-regression if appropriate. Heterogeneity was calculated using Higgins chi-square test and quantified by measuring I^2 (Higgins 2002). A chi-square test with a P-value of < 0.10 was considered to indicate the presence of heterogeneity, while an I^2 > 50% was considered to suggest a marked inconsistency in effect between studies. The fixed-effect model was only used if no heterogeneity was present. In all other cases the random-effects model was used. If excessive heterogeneity was present, data were re-checked first. If heterogeneity persisted, subgroup or sensitivity analyses were used to explore its causes. When adequate reasons were present extreme outliers were excluded in sensitivity analyses. In situations of excessive heterogeneity that could not be explained, we refrained from reporting a pooled estimate.

Assessment of reporting biases

We will use funnel plots to provide a visual assessment of whether treatment estimates are associated with study size. The presence of publication bias and other biases (Begg 1994; Egger 1997; Macaskill 2001) varies with the magnitude of the treatment effect, the distribution of study size, and whether a one- or two-tailed test is used (Macaskill 2001).

Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be performed to compare the effects of the interventions according to the methodological quality of the trials (adequate compared to unclear/inadequate for RCT's and according to the MINORS divided in low and high quality for observational studies). Furthermore, causes of contingent heterogeneity (defined as the presence of statistical heterogeneity by chi-squared test with significance set at P-value < 0.10 and measured by the quantities of heterogeneity by I2 (Higgins 2005, section 8.7.2)) will be explored by comparing different groups of trials stratified to, level of experience of the surgeon, and other factors that may explain heterogeneity. Subgroup analysis will be performed on three seperate parameters; 1: subgroup analysis between open and laparoscopic surgery with ERAS, to investigate the effect of laparoscopic intervention. 2: subgroup analysis between colon and rectal procedures, especially since initial investigation suggests most literature to concern colonic resections. 3: stratification between true ERAS protocols and other recovery strategies. An ERAS protocol will be considered true when a minimal set of interventions is used (ie. epidural analgesia, early oral diet and mobilisation)

ACKNOWLEDGEMENTS

none

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Search strategies

Database	search strategie
The Cochrane Library	((fast AND track) OR (ERAS) OR (Enhanced AND recovery AND Surgery)) AND (colorectal OR colon OR Rectum OR Sigmoid) AND (surgery OR surgical OR procedure)
Pubmed	((fast AND track) OR (ERAS) OR (Enhanced AND recovery AND Surgery) OR (”fast track“)) AND (colorectal OR colon OR Rectum OR Sigmoid) AND (surgery OR surgical OR procedure) (surgery[TIAB]ORsurgery [MH]ORsurgery[Subheading]ORsurgical[TIAB]ORsurgically[TIAB]ORlaparoscopy[TIAB]OR laparoscopy [MH] OR laparoscopic [TIAB] OR laparoscopically [TIAB] OR colorectal surgery [MH] OR surgical procedures, operative [MH] OR Surgical Procedures, Minor [MeSH]) AND (Randomized Controlled Trial [pt] OR Controlled Clinical Trial [pt] OR Randomized Controlled Trials [mh] OR RandomAllocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh]OR (\clinical trial” [tw]) OR ((singl* [tw] OR doubl* [tw] OR trebl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind*[tw])) OR (placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp] OR comparative study [mh]OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR control* [tw] OR prospectiv* [tw]OR volunteer* [tw]) NOT (animals [mh] NOT human [mh]))
Embase	Search strategy will be conducted through the advanced search feature of EMBASE, with the next options tagged on: -Map to preferred terminology -Also search as keyword-Include sub-terms/derivatives (explosion search) -1990 - 2006 -EMBASE Only

Table 1. Search strategies (*Continued*)

	((fast AND track) OR (ERAS) OR (Enhanced AND recovery AND Surgery) OR ("fast track");ti,ab) AND (\surgery":ti,ab OR \surgical":ti,ab OR \surgically":ti,ab OR \surgery"/exp OR\laparoscopy":ti,ab OR \laparoscopic":ti,ab OR \laparoscopically":ti,ab OR \laparoscopy") AND ((colorectal OR colon OR Rectum OR Sigmoid);ti,ab) AND (\randomization"/exp OR \controlled clinical trial"/exp OR \randomized controlled trials"/exp OR \random allocation"/expOR \double-blind method"/exp OR \single-blind method"/exp OR \clinical trials"/exp OR \clinical trial":ti,ab ORRandom* :ti,ab OR \comparative studies"/exp OR \evaluation studies"/exp OR \follow-up studies"/exp OR \prospectivestudies"/exp OR control* :ti,ab OR prospectiv* :ti,ab OR volunteer* :ti,ab)
ISI WEb of Knowledge	#1 (Fast and Track) OR (ERAS) OR (enhanced AND recovery AND surgery) #2 (colorectal) OR (colon) OR (rectum) OR (rectal) OR (sigmoid) #3 (randomized controlled trial OR controlled clinical trial OR randomized controlled trials OR random allocation ORdouble-blind method OR single-blind method OR clinical trial OR clinical trials OR clinical trial OR ((singl* OR doubl*OR trebl* OR tripl*) AND (mask* OR blind*)) OR placebos OR placebo* OR random* OR comparative study OREvaluation stud* OR follow-up stud* OR prospective stud* OR control* OR prospectiv* OR volunteer*) #4 (#1 AND #2 AND #3)
Webcasts of the anual meeting of ACRS	Full manual search

Table 2. Modified Methodological index for non-randomised tables (MINORS)

Item*
1. Inclusion of consecutive patients: all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)
2. Prospective collection of data: data were collected according to a protocol established before the beginning of the study
3. Unbiased assessment of the study endpoint: blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated
4. Follow-up period appropriate to the aim of the study: the follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events
5. Loss to follow up less then 5%^: all patients should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint; or if the numbers and reasons for dropouts and withdrawals in all intervention groups were described
6. An adequate control group: having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data

Table 2. Modified Methodological index for non-randomised tables (MINORS) (*Continued*)

7. Contemporary groups: control and studied group should be managed during the same time period (no historical comparison)
8. Baseline equivalence of groups **: the groups should be similar regarding the criteria other than the studied endpoints, i.e. absence of confounding factors that could bias the interpretation of the results

* Items were scored 'adequate' if condition was satisfied, 'inadequate' if condition was not satisfied and 'unclear' if information regarding item was not reported.

^ Measured at time of discharge, since most trials only followed patients until discharge.

** In this review baselines of the two groups should be equivalent regarding age, gender, BMI and distribution of treatment modality (conventional/fast track).

HISTORY

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CONTRIBUTIONS OF AUTHORS

- W.R Spanjersberg, Netherlands Writing manuscript, methodological setup, developing search strategies, performing literature search, evaluate identified trials, statistical analysis

DECLARATIONS OF INTEREST

none