Laparoscopic ileocolic resection versus infliximab treatment of recurrent distal ileitis in Crohn's disease: a randomized multicenter trial (LIR!C-trial).

No registrations found.

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

Summary

ID

NL-OMON21700

Source
Nationaal Trial Register

Brief title
LIR!C-trial (LIRIC-trial)

Health condition

Engels: recurrent Crohn´s disease located in the terminal ileum, infliximab, ileocolic resection, QALY, Laparoscopy.
(NLD: recidiverende ziekte van Crohn in het terminale ileum, infliximab, ileocecaal resectie, QALY, laparoscopie).

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

1. Disease-specific quality of life, as measured with the IBDQ;

2. Costs per QALY.

Secondary outcome

1. General quality of life, as measured by the SF-36 and EuroQol 5D questionnaires;

2. Number of days on sick leave;

3. Days unable to participate in social life;

4. Morbidity (due to either surgery or medical treatment);

5. Total in and out hospital medical and non-medical costs;

6. Body image and cosmesis as measured by the body image questionnaire.

Study description

Background summary

Recurrent Crohn’s disease, defined as disease refractory to immunomodulatory agents that has been treated with steroids, is generally treated with infliximab. Once started infliximab should be given at regular 6 to 12 weeks intervals and is combined with other immunosuppressive drugs. Infliximab is an expensive treatment and it is currently unknown how long the treatment should be continued. Patients that need this type of treatment have a reduced quality of life. Surgical resection is an accepted alternative treatment. Laparoscopic ileocolic resection is as safe as open surgical resection, yielding shorter hospitalization and better cosmesis. Therefore, when disease activity is limited to the ileum this intervention maybe cheaper, more effective and resulting in a better quality of life.
The objective of this project is a comparison of the effectiveness and costs of infliximab treatment with laparoscopic ileo-colic resection in patients with recurrent Crohn’s disease of the distal ileum.
The study is designed as a multicenter randomized clinical trial including patients with Crohn’s disease located in the terminal ileum that require infliximab treatment following recent consensus statements on IBD treatment: moderate to severe disease activity in patients that fail to respond to steroid therapy or immunomodulatory therapy. Patients will be randomized to receive either infliximab or undergo a laparoscopic ileocolic resection. Primary outcomes are defined as costs and treatment efficacy defined by hospital stay, early and late

morbidity, sick leave, quality of life and surgical recurrence.. In order to detect an effect size of 0.5 on the IBDQ at a 5% two sided significance level with a power of 80% a sample size of 65 patients per treatment is estimated. An economic evaluation will be performed by assessing the marginal direct medical, non-medical and time costs will be compared and the costs per QALY calculated. For both treatment strategies a cost-utility ratio will be calculated. Patients will be included from November 2007 until November 2009.

Study objective

Laparoscopic ileocolic resection may be more effective than infliximab treatment in recurrent Crohn´s disease located in the terminal ileum improving quality of life and reducing costs.

Study design

N/A

Intervention

1. Infliximab: remission induction - three subsequent infusions at week 0, 2 and 6 in a dose of 5 mg/kg; maintenance therapy - infusions of 5 mg/kg at 8 to 12 weeks intervals in case of active disease after infliximab remission induction treatment. In case of disease recurrence during infliximab treatment intervals will be shortened to 6 weeks and/or the dose level increased to 10 mg/kg;

2. Laparoscopic ileocolic resection: prior to surgery remission induction consisting of prednisolone 40 mg OD for two weeks, 30 mg OD during two weeks and 25 mg OD for 1 week, followed by a dose 20 mg OD Once steroid therapy has been tapered to a dose of 20 mg/day ileocolic resection can be performed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age in between 18 and 80 years;

2. recurrent Crohn's disease of the distal ileum;

3. a stable dose of immunomodulatory therapy for at least 8 weeks;

4. a completed IBDQ and EQ-5D before randomization;

5. informed consent.

Exclusion criteria

1. Prior ileocolic resection for Crohn's disease;

2. Obstructive Crohn's disease of the distal ileum requiring surgery;

3. diseased small bowel segment longer than 40 cm;

4. abdominal abscesses, fistula's and abdominal fluid collections;

5. ASA III en iV;

6. Co-morbidity requiring infliximab treatment.

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2007
Enrollment:	142
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2007
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	NL1115
NTR-old	NTR1150
Other	subsidie : 80-82310-98-08105
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A