

Planned relaparotomy versus relaparotomy on demand in abdominal sepsis: a randomised, multi-center, clinical trial

Submission date 10/02/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/03/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/01/2012	Condition category Digestive System	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

RELAP trial

Study objectives

Relaparotomy on demand strategy in patients with secondary peritonitis reduces the risk of 180-day poor outcome (death or readmission/surgical intervention for morbidity in survivors) compared to a strategy with planned relaparotomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethics Committee, Academic Medical Center, Amsterdam, The Netherlands and by the Dutch Central Committee on Research Involving Human Subjects (Dutch initials: CCMO).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Secondary peritonitis

Interventions

Planned relaparotomy versus relaparotomy on demand

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Poor outcome defined as death (all-cause mortality) or, in survivors, readmission or surgical intervention for disease-related morbidity (i.e., morbidity related to abdominal sepsis and its treatment) during a 180-day period after index laparotomy.

Secondary outcome measures

1. Duration of mechanical ventilation, Intensive Care Unit (ICU) and hospital stay, days outside the hospital in one year after index surgery, long-term morbidity (one year), quality of life, and Quality-Adjusted Life-Years (QALYs).
2. Medical and indirect costs comparing absolute volumes of resource utilization.

Overall study start date

01/12/2001

Completion date

31/08/2006

Eligibility

Key inclusion criteria

1. Patients with secondary peritonitis
2. Between 18 and 80 years
3. An Acute Physiology And Chronic Health Evaluation (APACHE) II score more than 10 (worst score in the first 24 hours of diagnosis)

Participating centres:

1. Academic Medical Center Amsterdam
2. University Medical Center Utrecht
3. Gelre Hospital Apeldoorn
4. Onze Lieve Vrouwe Gasthuis (OLVG) Amsterdam
5. St Lucas Andreas Hospital Amsterdam
6. Isala Klinieken Zwolle
7. A. Schweitzer Hospital Dordrecht
8. Bosch Medisch Centrum Den Bosch
9. Reinier de Graaf Gasthuis Delft

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

222 (+12 additional for anticipated drop-outs)

Key exclusion criteria

1. Age less than 18 or more than 80 years
2. Abdominal infection due to perforation after endoscopy operated within 24 hours
3. Abdominal infection due to an indwelling dialysis (Continuous Ambulatory Peritoneal Dialysis [CAPD]) catheter
4. Acute pancreatitis
5. Index laparotomy for peritonitis in another (referring, non-participating) hospital
6. Expected survival less than six months due to disseminated malignancy
7. Brain damage due to trauma or anoxia

Date of first enrolment

01/12/2001

Date of final enrolment

31/08/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1105 AZ

Sponsor information**Organisation**

Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Sponsor details

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Sponsor type

Research organisation

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) - Health Care Efficiency Research programme

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	1.Results	22/08/2007		Yes	No
Results article	results	23/12/2011		Yes	No