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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2004	**Overall study status** Completed	
Last Edited 03/01/2012	**Condition category** Digestive System	

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

948-02-028

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
Laan van Nieuw Oost Indie 334
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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