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Effects of Peri-Operative fluid Restriction in patients undergoing pancreatic surgery

Submission date 14/02/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 16/10/2015	**Condition category** Cancer	

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
NTR573

Study information

Scientific Title
Effects of Peri-Operative fluid Restriction in patients undergoing pancreatic surgery

Acronym
EPOR trial

Study objectives
Our hypothesis is that peri-operative fluid restriction will lead to a significant reduction of solid phase gastric emptying time measured by radionuclide scintigraphy, and a reduction in its related post-operative complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised, double blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Pancreatic cancer

Interventions
Restrictive peri-operative fluid management versus standardised peri-operative fluid management in Whipple surgery.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

The primary endpoint is defined as the reduction of minutes needed to achieve a 50% emptying of the stomach (T50) due to a restricted fluid infusion regime.

Secondary outcome measures
The secondary endpoints are the following:
1. Total amount used of furosemide (no prior usage)
2. Total amount used intra-operatively of noradrenalin
3. Blood urea and creatinine levels: a rise of more than 10% of pre-operative values measured at: pre-assessment versus day 1, 3 and 7 post-operatively
4. Albumin levels: day 1, 3 and 7 post-operatively
5. Nutritional intake (calculation by dietician)
6. Duration of hospital stay
7. The length of remaining duodenum will be measured during operation (distance between pylorus and duodeno-jejunostomy)

Overall study start date
01/03/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Age range >18 years
2. Male patients, or female patients of non childbearing potential or with adequate contraception
3. American Society of Anesthesiologists (ASA) classification I-IV
4. Patients who will undergo elective pancreatic surgery
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Age range: <18 years
2. ASA classification V
3. Emergency operations

4. Pregnancy
5. Breast feeding period
6. Informed consent missing
7. Alcohol abuse (more than 35 units a week)
8. Drug abuse (opiates, cocaine)
9. SaO2 <90% (room atmosphere), SpO2 <8 kPa
10. Presumed non cooperatives
11. Legal incapacity
12. Refusal to undergo epidural anaesthesia
13. Dialysis or fluid restriction based on renal failure
14. Any clinical condition which does not justify study participation in the investigator's opinion

Date of first enrolment
01/03/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (Netherlands)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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	results	14/10/2015		Yes	No