

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

Submission date 14/02/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 14/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/10/2015	Condition category Cancer	☐ 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

Protocol serial number
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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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