

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

<b>Submission date</b> 14/02/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/10/2015	<b>Condition category</b> Cancer	<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**  
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. SaO<sub>2</sub> <90% (room atmosphere), SpO<sub>2</sub> <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

Netherlands

1100 DD

**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?
<a href="#">Results article</a>	results	14/10/2015		Yes	No