Effects of Per-Operative fluid Restriction in patients undergoing pancreatic surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21304

Source
NTR

Brief title
EPOR trial

Health condition

Eligible patients for participation in this clinical trial are those planned to undergo elective pancreatico-duodenectomy

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam (AMC)
Source(s) of monetary or material Support: Internal funding

Intervention

Outcome measures

Primary outcome

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

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 vs. day 1, 3 and 7 postoperatively;
4. Albumin levels: day 1, 3 and 7 postoperatively;
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).

Study description

Background summary

Studies have shown that large volume infusions, especially when given during major surgical procedures, influence the outcome of these operations. There is evidence supporting the view that fluid restriction has a beneficial effect on several parameters.
AIM:
Our primary aim is to ascertain whether the gastric emptying time can be improved by a peroperative restrictive fluid regime. Our secondary aim is to see whether there is any difference between the two groups in: use of furosemide, noradrenaline, postoperative renal function, food intake and duration of hospital stay.
Patients and Methods:
Eligible patients will be randomised, and will be treated during the operation with a restrictive or standard fluid regime. They will undergo a gastric emptying scan 1 day preoperatively, and also 7 days postoperatively, after ingesting a standardised test meal.

Study objective

Our hypothesis is that peroperative fluid restriction will lead to a significant reduction of solid phase gastric emptying time ¨C measured by radionuclide scintigraphy-, and a reduction in its related postoperative complications.

Intervention

Restrictive peroperative fluid management and standardised peroperative fluid management in Whipple surgery.

Contacts

Public
Academic Medical Center (AMC), Department of Anesthesiology, H1- 128,
P.O. Box 22660
G. Samkar, van
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center (AMC), Department of Anesthesiology, H1- 128,
P.O. Box 22660
G. Samkar, van
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Age range ¡Ý 18 years;
2. Male patients, or female patients of non childbearing potential or with adequate contraception;
3. ASA classification I ¨C IV;
4. Patients who will undergo elective pancreatic surgery;
5. Written informed consent.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2006
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	27-01-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL529
NTR-old	NTR573
Other	: N/A
ISRCTN	ISRCTN62621488

Study results

Summary results
N/A