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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21304

Bron
NTR

Verkorte titel
EPOR trial

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam (AMC)
Overige ondersteuning: Internal funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-01-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A