FLUYT-trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22879

Source
Nationaal Trial Register

Brief title
FLUYT

Health condition

ERCP, pancreatitis, lactated Ringers solution, prevention

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Post-ERCP pancreatitis (Cotton criteria)

Secondary outcome

1) Severity of PEP (according to the Cotton classification)

2) Severe morbidity (according to the revised Atlanta criteria) and mortality.

3) ERCP-procedure related complications: bleeding, perforation, post-ERCP fever/ cholangitis/ cholecystitis

4) Ringer's lactated solution hydration related complications, especially: pulmonary edema, cardiac insufficiency, peripheral edema,hypernatremia and renal failure. All adverse events will be monitored, according to good clinical practice (GCP).
5) Length of hospital and intensive care unit (ICU) stay.

6) Direct (non)medical costs, indirect costs, among others by using iMTA PCQ questionnaire

7) Generic health related quality of life measured with the EQ5D and the SF36

8) Risk-factors for PEP development: pre-ERCP BUN levels, validation of already known risk factors, BMI,
smoking behavior, co-morbidity (diabetes, cardiovascular disease, ect.), sedation type (midazolam,
propofol, fentanyl), social/ economic status, race.

9) Exocrine and endocrine pancreatic insufficiency at 180 days in patients who had developed PEP: fecal
elastase-1 <200 ìg/L, HbA1c >42 mmol/mol.

10) Incidence of delayed PEP (PEP >48h after the procedure).

Study description

Study objective

Peri-procedural intensive RL hydration on top of RN will reduce the incidence of PEP in a moderate-high risk population, and may even reduce the percentage of severe PEP. This may improve patients' health status,
prevent serious complications of PEP, reduce the demand for healthcare, and will lower costs. We hypothesize that this peri-procedural intensive RL hydration therapy is superior to usual care with respect to patient outcomes (PEP).

Study design

1) Patient-related quality of life: at 30, 90 and 180 days

2) Exocrin and endocrin pancreatic insufficiency at 180 days

Intervention

Intervention: Ringer's lactated solution

Control: NaCl 0.9%

Contacts

Public
Datacenter Pancreatitis Werkgroep Nederland - Huispost PWN

Xavier Smeets
Postbus 2500

Nieuwegein 3430 EM
The Netherlands
088-320 7054
Scientific
Datacenter Pancreatitis Werkgroep Nederland - Huispost PWN

Xavier Smeets
Postbus 2500

Nieuwegein 3430 EM
The Netherlands
088-320 7054

Eligibility criteria

Inclusion criteria

1) Age 18-85

2) Indication for ERCP

3) Written Informed Consent

Exclusion criteria

1) Allergy to NSAID’s or other contraindications

2) Ongoing acute pancreatitis

3) Ongoing hypotension, including those with sepsis

4) Cardiac insufficiency (>NYHA Class I heart failure)

5) Renal insufficiency (RI, creatinin clearance 40ml/min)

6) Active ulcer disease

7) Severe liver dysfunction: Liver cirrhosis and ascites

8) Respiratory insufficiency (pO2<60mmHg or 90% despite FiO2 of 30% or requiring mechanical ventilation).

9) Pregnancy

10) Hyponatremia (Na+ levels < 130mmol/l)

11) Hypernatremia (Na+ levels > 150mmol/l)

12) Oedema

13) Low risk of PEP: chronic calcific pancreatitis or pancreatic head mass or routine biliary stent exchange; reERCP
with a history of endoscopic sphincterotomy with a CBD intervention (PD intervention is allowed)

14) Planned prophylactic pancreatic stent placement

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2015

Enrollment:	826
Type:	Anticipated

Ethics review

Positive opinion Date:	08-06-2015
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	NL5020
NTR-old	NTR5166
Other	ABR NL52341.100.15 : ISRCTN13659155

Study results