Fluid hydration to prevent post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis: the FLUYT-prevent trial. a multicenter randomized controlled superiority trial.;Pancreatic duct stent placement to prevent post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis in patients with unintended PD-wire cannulation: a multicenter prospective cohort

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FLUYT: To investigate whether aggressive rehydration with RL during ERCP prevents PEP and will be cost-effective.FLUYT-2-PDS: To investigate if PDS placement further reduce the risk of the development of PEP in patients with unintended PD-wire...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON54543

Source
ToetsingOnline

Brief title
FLUYT-prevent trial

FLUYT -2-PDS

Condition

- Gastrointestinal inflammatory conditions

Synonym
post-ERCP pancreatitis; inflammation of the pancreas following ERCP

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: ERCP, Pancreatitis, Prevention, Ringer's lactate

Outcome measures

Primary outcome

FLUYT+ FLUYT-2-PDS: post-ERCP pancreatitis

Secondary outcome

FLUYT+ FLUYT-2-PDS:

-severity of post-ERCP pancreatitis

-morbidity

-mortality

-ERCP related complications (bleeding, perforation, cholangitis)

-oedema

-hyperhydration (pulmonary)

-total length of stay

-Quality of life

-cost effectiveness and utility

-pancreatic insufficiency

Additionally in FLUYT-2-PDS:

PDS placement failure

gastroscopy needed to remove the PDS

How often does a patient develop PEP after PDS removal

Study description

Background summary

FLUYT:
Yearly 17.000 endoscopic retrograde cholangiopancreatographies (ERCP) are performed in the Netherlands. The most prevalent complication is post-ERCP pancreatitis (PEP) with an incidence between 3% and 16%. PEP leads to prolonged hospitalization with substantial economic impact. Rectal NSAID*s (RN) carry the most solid evidence in decreasing the PEP rate and is the current standard of care according to the European Society of Gastrointestinal Endoscopy guideline. Still a PEP incidence of around 8% is seen. A new strategy to prevent PEP was performed by a pilot, randomized study comparing standard intravenous (IV) fluid administration with an aggressive rehydration protocol with Ringer*s lactate (RL). A positive effect on the incidence of PEP was seen in the RL group (17% standard vs 0% RL, p=0.016). Major limitations of this monocenter study are the limited amount of subjects included and that none of these subjects received RN. The current study investigates the value of peri-ERCP hydration with RL on top of standard care (RN) in preventing PEP and the cost-effectiveness of this intervention.

FLUYT-2-PDS
PD-wire cannulation will occur more and more in the future because of the preferred guide-wire assisted cannulation and the superiority of double wire assisted cannulation compared to PD stent assisted cannulation. We think that the efficacy of PDS in PEP prevention can potentially be increased, by limiting the use of PDS to cases with unintentional PD cannulation during the ERCP procedure, because of:
1. Less PDS failure rates (once you are in the PD, stent placement is usually easy).

2. PD-wire cannulation is considered as one of the most dominant procedure related PEP risk factor, which increases the PEP incidence. The cases will probably benefit the most of and additional PD stent.

Study objective

FLUYT: To investigate whether aggressive rehydration with RL during ERCP prevents PEP and will be cost-effective.

FLUYT-2-PDS: To investigate if PDS placement further reduce the risk of the development of PEP in patients with unintended PD-wire cannulation already using prophylactic RN and thereby minimize costs related to complications of ERCP.

Study design

FLUYT: A multicenter, randomized controlled trial.

FLUYT-2-PDS: A multicenter prospective cohort

Intervention

FLUYT: Patients in the intervention group will receive 20cc/kg Ringer's lactate within 60 minutes at the start of ERCP (scope-mouth contact), followed by 3cc/kg/hour during 8 hours post ERCP AND rectal NSAID
Patients in the control group will receive the standard amount of fluid with a rectal NSAID.

FLUYT-2-PDS: not applicable

Study burden and risks

FLUYT: The patients burden is pre and post procedural blood urine sampling, body measurements and a questionnaire (15min) 30 days after the procedure. During follow-up, a stool sample will be asked from patients who developed post-ERCP pancreatitis, as well as a blood sample for HbA1c measurement. Possible risks are associated with hyperhydration (i.e. pulmonary edema, ankle edema). However, considering the total volume of fluids used and the exclusion of patients prone to this complication, the risk should be very low. It must be stressed that there is no standard infusion rate, volume and type of fluid, in the peri-ERCP setting. The two regimens proposed in this study are within the range daily common practice use.

FLUYT-2-PDS: The patients burden is pre and post procedural blood urine sampling and body measurements. During follow-up, a stool sample will be asked from patients who developed post-ERCP pancreatitis, as well as a blood sample

for HbA1c measurement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 to 85
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, GFR <30ml/min) 6) Active ulcer disease 7) Severe liver dysfunction: Liver cirrhosis and currently 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 (according to M-ANNHEIM criteria) with a CBD intervention (PD intervention is allowed --> not in FLUYT-2-PDS); or pancreatic head mass; or routine biliary stent exchange; or re-ERCP with a history of endoscopic sphincterotomy with a CBD intervention (PD intervention is allowed --> not in FLUYT-2-PDS) 14) Planned prophylactic pancreatic stent placement 15) Altered anatomy, defined as anatomical variations in which gall and/or pancreatic juices (in case of pancreatic duct interventions) do not enter the duodenum by way of the ampulla of Vater. This is the case after surgical interventions such as Roux-Y reconstruction, surgery for chronic pancreatitis, gastric bypass or surgical ampullectomy. 16) Patients receiving more than 1.5ml/kg/hr of intravenous fluids before ERCP

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2015
Enrollment:	1108
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-11-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-06-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
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Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-10-2021

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	09-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ISRCTN	ISRCTN13659155
CCMO	NL52341.100.15