

FLUYT-prevent trial

Submission date 04/03/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/03/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Every year 17,000 endoscopic retrograde cholangiopancreatographies (ERCP) are performed in the Netherlands. ERCP is a procedure to evaluate and treat conditions concerning the bile duct. The most common complication is post-ERCP pancreatitis (PEP), occurring in 3%-16% of patients undergoing the procedure. PEP leads to prolonged hospitalization with substantial economic impact. Rectal anti-inflammatory drugs carry the most solid evidence in decreasing the PEP rate and this is the current standard of care according to the European Society of Gastrointestinal Endoscopy guideline. A new strategy to prevent PEP was tested in a study which compared standard intravenous (IV) fluid administration with an aggressive rehydration protocol with Ringer's lactate (RL, a type of infusion fluid). However, the limitations of the study were the small number of patients involved and the fact that none of them received anti-inflammatory drugs. The aim of this study is to investigate the value of peri-ERCP hydration with RL on top of standard care, including anti-inflammatory drugs.

Who can participate?

Patients between 18 and 85 years of age undergoing ERCP with a moderate-severe risk for developing PEP

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives intensive RL hydration in addition to rectal anti-inflammatory drugs. The other group receives no or mild hydration with normal saline (salt water) in addition to rectal anti-inflammatory drugs (the standard of care). Participants have the following tests: blood sampling, body measurements and a questionnaire (15-30 min) at 30, 90 and 180 days after the procedure.

What are the possible benefits and risks of participating?

Possible risks are associated with overhydration (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.

Where is the study run from?

A number of hospitals in the Netherlands

When is the study starting and how long is it expected to run for?
April 2015 to November 2016

Who is funding the study?

1. Radboud University Medical Center
2. Netherlands Organisation for Health Research and Development

Who is the main contact?

Dr Erwin van Geenen
erwin.vangeenen@radboudumc.nl

Study website

<https://www.fluyt-trial.nl/>

Contact information

Type(s)

Scientific

Contact name

Dr Erwin van Geenen

Contact details

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Additional identifiers

EudraCT/CTIS number

2015-000829-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 2 (dated 09/03/2015)

Study information

Scientific Title

Fluid hydration to prevent post-endoscopic retrograde cholangiopancreatography pancreatitis

Acronym

FLUYT-prevent

Study objectives

Peri-procedural intensive lactated Ringer's solution hydration on top of rectal non-steroid anti-inflammatory drugs will reduce the incidence of post-ERCP pancreatitis (PEP) in a moderate-to-high risk population, and may even reduce the percentage of severe PEP.

Ethics approval required

Old ethics approval format

Ethics approval(s)

On the 14/04/2015, the Medical research Ethics Committees United (MEC-U) gave a positive verdict for the trial. Also, as a Competent Authority for the review of clinical trials in the Netherlands, the CCMO has performed a marginal assessment of the clinical trial. The Competent Authority found no objection against execution of the trial within the Netherlands. This verdict was given on 06/05/2015.

Study design

Multicenter randomized superiority trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Choledocholithiasis and other conditions requiring endoscopic retrograde cholangiopancreatography (ERCP)

Interventions

High volume intravenous hydration with lactated Ringer's solution

Added 17/02/2017:

Participants are randomised to one of two treatment arms:

1. Control group: 100mg rectal NSAID + no or mild hydration with normal saline (max 1.5mL/kg/hr, max. 3L/24h)
2. Intervention group: 100mg rectal NSAID + hydration with lactated Ringer's solution (20mL/kg <60min, starting at the beginning of ERCP (scope-mouth contact), followed by 3mL/kg/hr for 8 hours)

Patients are discharged after ERCP after a minimal clinical stay of 24 hours. It is at the discretion of the treating physician whether an admission or longer monitoring is indicated. All patients are followed up for 180 days after randomization.

Intervention Type

Mixed

Primary outcome measure

Post-ERCP pancreatitis, according to Cotton criteria

Secondary outcome measures

1. Severity of post-ERCP pancreatitis measured at discharge (Cotton criteria)
2. Severe morbidity (Atlanta criteria) or death measured at discharge
3. ERCP related complications within 48 hours after ERCP
4. Fluid hydration related complications within 24 hours after ERCP or at the latest at discharge
5. Length of hospital stay (including stay on the intensive care unit) measured after a follow up period of 6 months (so readmissions can be taken into account)
6. Direct and indirect costs measured after 6 months of follow up
7. Risk factors for developing post-ERCP pancreatitis measured at baseline
8. Generic health-related quality of life measured with EQ5D and SF36
9. Exocrine and endocrine pancreatic insufficiency at 180 days: fecal elastase-1 and HbA1c
10. Incidence of delayed post-ERCP pancreatitis

Overall study start date

01/04/2015

Completion date

03/12/2019

Eligibility

Key inclusion criteria

1. Requiring ERCP
2. Between 18 and 85 years of age
3. Signed informed consent

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

826 patients

Total final enrolment

826

Key exclusion criteria

1. Allergy to NSAIDs or other contraindications
2. Ongoing acute pancreatitis
3. Ongoing hypotension, including those with sepsis
4. Cardiac insufficiency (CI, >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 (PD intervention is allowed) or pancreatic head mass or routine biliary stent exchange or re-ERCP with a history of endoscopicsphincterotomy with a CBD intervention (PD intervention is allowed)

Date of first enrolment

05/06/2015

Date of final enrolment

01/08/2019

Locations**Countries of recruitment**

Netherlands

Study participating centre

Radboud University Medical Center

Nijmegen

Netherlands

-

Study participating centre

St. Antonius Hospital

Nieuwegein

Netherlands

-

Study participating centre

Antoni van Leeuwenhoek Hospital

Amsterdam
Netherlands

-

Study participating centre

Jeroen Bosch Hospital

's Hertogenbosch
Netherlands

-

Study participating centre

Onze Lieve Vrouwe Gasthuis

Amsterdam
Netherlands

-

Study participating centre

Erasmus Medical Center

Rotterdam
Netherlands

-

Study participating centre

Isala Clinics

Zwolle
Netherlands

-

Study participating centre

Spaarne Hospital

Haarlem
Netherlands

-

Study participating centre

Medisch Spectrum Twente Hospital
Enschede
Netherlands
-

Study participating centre
Univeristy Medical Center Utrecht
Utrecht
Netherlands
-

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
-

Study participating centre
Albert Schweitzer Hospital
Dordrecht
Netherlands
-

Study participating centre
Amphia Hospital
Breda
Netherlands
-

Study participating centre
Canisius Wilhelmina Hospital
Nijmegen
Netherlands
-

Study participating centre

Diakonessenhuis

Utrecht

Netherlands

-

Study participating centre

Gelderse Vallei Hospital

Ede

Netherlands

-

Study participating centre

HAGA hospital

Den Haag

Netherlands

-

Study participating centre

Maasstad hospital

Rotterdam

Netherlands

-

Study participating centre

Martini hospital

Groningen

Netherlands

-

Study participating centre

Meander Medical Centre

Amersfoort

Netherlands

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Study participating centre

Rijnstate Hospital

Arnhem
Netherlands

-

Study participating centre**Zuyderland Hospital**

Heerlen
Netherlands

-

Sponsor information

Organisation

Radboud University Medical Center

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

www.radboudumc.nl

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Radboud University Medical Center, Department of Gastroenterology and Hepatology

Funder Name

Netherlands Organisation for Health Research and Development

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

A manuscript with the study results will be sent to a peer-reviewed journal for publication in Q4 /2019-Q1/2020, regardless of the outcome. Around the same date, an abstract will be sent to international congresses such as the DDW and UEGW.

Intention to publish date

01/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Erwin van Geenen (Erwin.vangeenen@radboudumc.nl).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/04/2018		Yes	No
Results article		01/05/2021	22/03/2021	Yes	No