Combination of discharge algorithm and trypsinogen-2 urine dipstick to safely discharge patients after endoscopic retrograde cholangiopancreatography (ERCP)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22334

Source
NTR

Brief title
ERCP- Discharge study

Health condition

Post-ERCP pancreatitis

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Radboud universuty medical center

Intervention

Outcome measures

Primary outcome

Asses the sensitivity and specificity of an ERCP discharge tool that combines a discharge algorithm and urinary trypsinogen-2 dipstick.

Secondary outcome

1) Endoscopist and patient attitudes (measured by PREM questionnaire) towards discharge tool combined with urinary dipstick testing.
2) Identification of factors that lead to false positives and negatives of the trypsinogen-2 urinary dipstick.
3) Overall cost reduction obtained by safe early discharge.

Study description

Background summary

The most commonly occurring complication of an endoscopic retrograde cholangiopancreaticography (ERCP) is that of the post-ERCP pancreatitis (PEP), with an incidence of 3.5%-9.7%. Approximately 90% of the cases have a mild to moderately severity, although there is still a chance of 1-3% mortality in this group of patients. There is little consensus on which patients are merited by a longer observation period post-procedural, which results in a large variance between hospitals of those who are admitted post-ERCP. Most patients can be discharged under guidance after 2 hours of recovery, but it is essential to identify the patients at high risk for complications such as PEP.
Research question: What is the added value of an urinary trypsinogen-2 dipstick to an already established ERCP discharge tool by Jeurnink et al.?
Objective: To evaluate the ERCP discharge tool in combination with a urinary trypsinogen-2 dipstick test in the early identification of patients at risk for developing a post-ERCP pancreatitis.

Study objective

ERCP discharge algorithm combined with UT-2 dipstick test (with a cutoff value of 50µg/ml) can accurately distinguish between groups warranting early discharge and those warranting observation post-ERCP.

Study design

Primary: 2 hours after ERCP
Secondary: Day 0- 5 days after ERCP or until discharge

Intervention

Urine dipstick 2 hours after scope-mouth contact of ERCP + patient reported experience

measurement at day of discharge

Contacts

Public
Radboudumc
Christa Sperna Weiland

0883207054
Scientific
Radboudumc
Christa Sperna Weiland

0883207054

Eligibility criteria

Inclusion criteria

- Patients undergoing ERCP
- Age >18 years

Exclusion criteria

- Ongoing acute pancreatitis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2018
Enrollment:	260
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	30-03-2020
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	NL8486
Other	CMO Radboudumc : 2018-4431

Study results

Summary results
N/A