The diagnostic performance of different diagnostic tests to detect post-ERCP pancreatitis: trypsinogen-2 urinary dipstick test and serum trypsinogen-2, amylase, lipase and a prediction model

Published: 25-03-2010
Last updated: 06-05-2024

Primary objective: - To evaluate the diagnostic performance of the urinary trypsinogen-2 test for post-ERCP pancreatitisSecondary objectives: - To evaluate the diagnostic performance of serum trypsinogen-2, serum amylase/lipase for post-ERCP...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35470

Source
ToetsingOnline

Brief title
ERCP-study

Condition

- Other condition
- Bile duct disorders

Synonym
pancreatitis, post-ERCP pancreatitis

Health condition

post ERCP pancreatitis en cholangitis, perforatie of bloeding post-ERCP.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,de dipstick tests worden gratis beschikbaar gesteld door Medix Biochemica,Medix Biochemica (Finland): zal de trypsinogeen-2 ELISA en urine dipstick tests gratis ter beschikking stellen

Intervention

Keyword: Day care ERCP, ERCP, Post-ERCP pancreatitis, Urinary trypsinogen-2 dipstick test

Outcome measures

Primary outcome

Post ERCP pancreatitis

Secondary outcome

Post ERCP cholangitis

Post ERCP perforation

Post ERCP hemorrhage

Study description

Background summary

ERCP is generally followed by overnight observation for potential complications. However, more than 90% of patients do not develop complications and do not need the overnight stay. Several serum and urine markers have been tested for prediction of early diagnosis and severity of pancreatitis. Serum trypsinogen-2 and the urinary trypsinogene-2 dipstick test (UTDT) have been evaluated to diagnose pancreatitis in emergency settings and seem to be accurate diagnostic tests. In addition, the dipstick test is easy in use without any burden to the patient. The serum test has the potential advantage that it provides a continuous outcome, which might say something about severity of the pancreatitis. Other serum markers have been tested for prediction of early diagnosis and severity of pancreatitis as well. Serum markers, like lipase and amylase (with various cut-off points) can be considered as an early

diagnostic test. A drawback of serum amylase and lipase is that these markers peak in nearly every patient between 1.5-4 hours post ERCP. The swiftness and degree of the elevation, however, can be an indicator for patients developing PEP.
Another way to predict the occurrence of post-ERCP pancreatitis is by a risk model based on patient - and procedure related factors. A risk model has been designed to select patients at high and low risks for complications, such as post-ERCP pancreatitis (PEP). This model was designed in another center and will be tested on accuracy of prediction of development of post ERCP pancreatitis in our medical center.
A comparison of serum and urinary trypsinogen-2 tests, serum amylase and a prediction model to evaluate the most accurate predictor of post-ERCP pancreatitis has not yet been performed. futhermore, both models will be compared for agreement and to detect the most accurate model. Detecting the most accurate, early diagnostic test and cut-off point can (in the future) help selecting patients eligible for early discharge after ERCP.

Study objective

Primary objective:
- To evaluate the diagnostic performance of the urinary trypsinogen-2 test for post-ERCP pancreatitis
Secondary objectives:
- To evaluate the diagnostic performance of serum trypsinogen-2, serum amylase/lipase for post-ERCP pancreatitis
- To identify other patient- and procedure related risk factors for post-ERCP pancreatitis
- To create a multivariate model with independent predictors for post-ERCP pancreatitis
- To evaluate the performance of existing prediction model (designed in Rotterdam) for post-ERCP pancreatitis
- To compare the existing prediction model to our multivariate model.

Study design

Prospective, observational study.
Urine and blood samples (2*9 ml) will be collected before and 2 hours after ERCP. Blood samples collected before ERCP are part of routine patient care. A risk score will be calculated after ERCP based on patient and procedure related risk factors. The treating physician will be kept blind for the test results.
Minor complications (nausea, pain and discomfort) will be measured (according to standardized questionnaires) 2 hours and 24 hours after ERCP. All patienst will admitted for overnight observation.
On day 7 and 30 patients are contacted by telephone to evaluate complications, symptoms, additional use of medication, hospital admission or visits to the

general practitioner (according to standardized questionnaires).

Study burden and risks

Risks: the risk of drawing a blood sample is negligible.

Burden: Urine and blood samples (2*9 ml) will be collected before and 2 hours after ERCP. Blood samples collected before ERCP are part of routine patient care. Minor complications (nausea, pain and discomfort) will be measured (according to standardized questionnaires) 2 hours and 24 hours after ERCP. On day 7 and 30 patients are contacted by telephone to evaluate complications, symptoms, additional use of medication, hospital admission or visits to the general practitioner (according to standardized questionnaires).

Benefit: For the subjects partcipating in the study: none
For the general population undergoing ERCP: Various diagnostic tests are examined to safely discharge outpatient ERCP patients, which hopefully leads to a more progressive and safe discharge strategy.

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

- Referred for ERCP
- 18 years and older
- Written informed consent

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL28135.041.09