Back to the beginning * the Amylon study: Serum amylase, urinary amylase and serum lipase for diagnosing acute pancreatitis

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to investigate the course of the pancreatic enzymes (serum amylase, serum lipase and urinary amylase) related to the course and stage of acute pancreatitis and thereby calculating the diagnostic accuracy of each pancreatic enzyme for acute...

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

Summary

ID

NL-OMON44831

Source
ToetsingOnline

Brief title
the Amylon study

Condition

- Other condition
- Gastrointestinal inflammatory conditions

Synonym
acute inflammation of the pancreas, Acute pancreatitis

Health condition

pancreasontstekingsaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfonds MCH

Intervention

Keyword: acute pancreatitis, serum amylase, serum lipase, urine amylase

Outcome measures

Primary outcome

The diagnostic accuracy (AUC/ROC) of serum amylase, serum lipase and urinary amylase for acute pancreatitis per day after onset of symptoms until day 5 and on day 7.

Secondary outcome

- difference in diagnostic accuracy (AUC/ROC) after subgroup analyses: different etiology of acute pancreatitis (f.e. alcohol induced, hyperlipidemia induced or biliary acute pancreatitis), and mild versus severe pancreatitis
- difference in diagnostic accuracy (AUC/ROC) in urinary amylase versus amylase creatinine clearance ratio
- difference in diagnostic accuracy (AUC/ROC) in one solitary pancreatic enzyme versus a combination of enzymes

Study description

Background summary

Acute pancreatitis is a common problem and a potentially fatal disease.
Diagnosing acute pancreatitis is difficult due to the lack of a gold standard.

The value of pancreatic enzyme measurement in acute pancreatitis has been debated abundantly in the last century. Nevertheless there are still limitations in using these enzymes in making the diagnosis acute pancreatitis.

Study objective

to investigate the course of the pancreatic enzymes (serum amylase, serum lipase and urinary amylase) related to the course and stage of acute pancreatitis and thereby calculating the diagnostic accuracy of each pancreatic enzyme for acute pancreatitis per day until day 5 and on day 7 after onset of symptoms.

Study design

Prospective single centre study

Study burden and risks

Daily collection of blood until day 5 and on day 7 after onset of symptoms is part of regular patient care in admitted patients. Extra urine portions will be collected daily. If patients are discharged within this period patients will be asked to collect urine and have blood withdrawal at the hospital. Collection of urine and blood withdrawal is without risk and of limited burden.
If not already done for diagnostic reasons, an extra contrast enhaced CT in all patients will be performed. There is a low risk for radiation-related secondary cancer development (lifetime attributable risk 0,05%). Contrast may cause allergy or nefrotoxicity (patients with chronic kidney disease will be excluded).

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

- hospitalized patients with acute onset of persistent, severe, epigastric pain
- aged *18 years
- able to provide written informed consent

Exclusion criteria

complaints starting more than 7 days before admission
chronic kidney disease (MDRD < 30ml/min)
pregnancy (serum beta hCG < 5U/l)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2014
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	16-04-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46840.098.14