Feasibility of the fecal Pancreas Elastase 1 Quick™ Test for exocrine pancreatic function testing

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28645

Source
NTR

Brief title
Quick study

Health condition

Pancreatic exocrine insufficiency

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Accuracy of the Quick test compared with the standard fecal Pancreas Elastase 1 test with ELISA

Secondary outcome

-

Study description

Study objective

To evaluate the feasibility the fecal Pancreas Elastase 1 Quick™ test (Quick test) for exocrine pancreatic function testing compared to standard fecal Pancreas Elastase 1 test with ELISA (ELISA test).

Study design

According to standard practice, the laboratory will perform the ELISA test (results available in 2-4 weeks). The coordinating investigator will collect and process the Quick test set and will report outcomes to the treating physician. The treating physician will report outcomes of the fecal elastase test to the patient when the results of the ELISA test are available.

Intervention

If a patient at the outpatient clinic has an indication for exocrine pancreatic function testing, the treating physician will request standard fecal elastase test according to standard practice. In addition, patients will be asked for informed consent to participate in the study. If a patient is willing to participate in the study, he will also receive a Quick Test set with an information brochure from the treating physician. The patient will be instructed to perform the Quick test from the same stool sample that will be used for the ELISA test.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with an indication for exocrine pancreatic function testing

- Verbal informed consent

Exclusion criteria

- <18 years old

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-08-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-08-2015
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	NL5196
NTR-old	NTR5344
Other	METC AMC : W15_194

Study results