

Diagnosis of cystic fibrosis fat malabsorption: fat absorption test.

No registrations found.

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

Summary

ID

NL-OMON21173

Source

NTR

Brief title

DLLT

Health condition

1. Cystic fibrosis;
2. fat malabsorption (NLD: vetmalabsorptie);
3. fecal fat balans (NLD: vetbalans);
4. pancreatic insufficiency (NLD: pancreasinsufficientie);
5. Lipolysis (NLD: lipolyse);
6. fat absorption (NLD: vetabsorptie).

Sponsors and support

Primary sponsor: Investigator initiated

Intervention

Outcome measures

Primary outcome

1. Fecal fat absorption coefficient;
2. Serum isotopes concentrations and appearance curves.

Secondary outcome

N/A

Study description

Background summary

The fecal fat balance is the current gold standard for evaluating fat malabsorption in CF patients. However there is a need for a simpler, sensitive and less restraining test to determine fat absorption in CF patients. More insight in the relative contribution of lipolysis and intestinal malabsorption of free fatty acids to fat malabsorption in CF patients would give way for a more directed therapeutic approach.

The aim of this study is to prove that the double labeled triglyceride and free fatty acid fat absorption test is as effective as the fecal fat balance as a quantitative diagnostic test for intestinal fat absorption in CF patients.

In the study we use triglyceride and free fatty acid both labeled with a different stable isotope. The double labeled triglyceride and free fatty acid fat absorption test is based on the principle of simultaneous admission of both the labeled triglyceride and labeled free fatty acids. The resulting appearance curve in the plasma determines the absorption of the separate components and is an indication for intestinal fat absorption.

Study objective

The double labeled triglyceride and free fatty acid fat absorption test is as effective as the fecal fat balance as a quantitative diagnostic test for intestinal fat absorption in CF patients.

Study design

N/A

Intervention

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

1. Cystic fibrosis patients;
2. Age: 2 -18 years;
3. Pancreatic insufficiency.

Exclusion criteria

1. Cystic fibrosis related liver disease;
2. Pulmonary (non-)infectious exacerbation;
3. Use of gastric acid-suppressive medications.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion	
Date:	06-02-2007
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

NTR-new

NTR-old

Other

ISRCTN

ID

NL877

NTR891

: 1

incomplete

Study results

Summary results

1. Rings EH, Minich DM, Vonk RJ, Stellaard F, Fetter WP, Verkade HJ.

Pediatr Res. 2002 Jan;51(1):57-63.

Functional development of fat absorption in term and preterm neonates strongly correlates with ability to absorb long-chain Fatty acids from intestinal lumen;

2. Kalivianakis M, Minich DM, Bijleveld CM, van Aalderen WM, Stellaard F, Laseur M, Vonk RJ, Verkade HJ.

Am J Clin Nutr. 1999 Jan;69(1):127-34.

Fat malabsorption in cystic fibrosis patients receiving enzyme replacement therapy is due to impaired intestinal uptake of long-chain fatty acids.

Bijvelds MJ, Bronsveld I, Havinga R, Sinaasappel M, de Jonge HR, Verkade HJ

Am J Physiol Gastrointest Liver Physiol. 2005 Apr;288(4):G646-53.

Fat absorption in cystic fibrosis mice is impeded by defective lipolysis and post-lipolytic events