Clinical evaluation of a new sweat test system in the diagnosis of cystic fibrosis after newborn screening

Published: 22-01-2009
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To determine the succes rate of the Nanoduct sweat test system.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON32874

Source
ToetsingOnline

Brief title
The nanoduct study

Condition

- Exocrine pancreas conditions
- Congenital respiratory tract disorders

Synonym
Cystic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Firma Wescor levert de benodigde apparatuur

Intervention

Keyword: Conductivity, Cystic Fibrosis, Nanoduct, Sweat test

Outcome measures

Primary outcome

Succes rate of the Nanoduct system.

Secondary outcome

Sensitivity, specificity, upper and lower cut-off values, time to diagnosis.

Study description

Background summary

A high chloride concentration determined in sweat is still the gold standard to confirm the diagnosis Cystic Fibrosis (CF). Validated methods for performing a sweat test are the Quantitative Pilocarpine Iontophoresis (QPIT) method and the Macroduct collection system. In young infants, for example neonates with a positive newborn screening test for CF (under 2 months of age), their often is an insufficient sweat sample. This may lead to a diagnostic delay and longer stressful period for the parents. The nanoduct is a new system for performing a sweat test, especially designed for neonates, but this method is not yet validated as a diagnostic instrument.

Study objective

To determine the succes rate of the Nanoduct sweat test system.

Study design

A prospective comparing study tot determine the success rate of the Nanoduct versus the QPIT/Macroduct.

Intervention

QPIT or Macroduct sweat test ('gold standard' test) and Nanoduct.

Study burden and risks

All infants undergo two tests instead of one, one on each arm at the same time. The sweat test is not painful nor distressing. the risk for complications is negligible, the only reported risk is redness of the skin when the test is not performed according to protocol or performed by non-skilled personell.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Newborns referred to the hospital for a sweat test after newborn screening. Children aged less than 2 months with a suspected diagnosis of Cystic Fibrosis. Informed consent has been obtained from the parents.

Exclusion criteria

Newborns with severe eczema, sepsis or dehydration (sweat test results are not reliable). Infants with meconium ileus. Informed consent can not be obtained.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-01-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-02-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-06-2009

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-09-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL25917.000.08