The Nanoduct study: a new sweat test system tested

Published: 26-06-2008 Last updated: 07-05-2024

To determine the reliability and feasibility of the Nanoduct sweat test system compared to the gold standard tests QPIT and Macroduct.

Ethical review Not approved **Status** Will not start

Health condition type Exocrine pancreas conditions

Study type Interventional

Summary

ID

NL-OMON31574

Source

ToetsingOnline

Brief title

The Nanoduct study

Condition

- Exocrine pancreas conditions
- Appetite and general nutritional disorders
- Congenital respiratory tract disorders

Synonym

Cystic Fibrosis, mucoviscoidosis

Research involving

Human

Sponsors and support

Primary sponsor: RIVM

Source(s) of monetary or material Support: Wescor

Intervention

Keyword: Conductivity, Cystic Fibrosis, Nanoduct, Sweat test

Outcome measures

Primary outcome

Primary endpoint: Failure rate of the Nanoduct.

Secondary outcome

Secondary endpoints: sensitivity, specificity, upper and lower cut-off points,

time to diagnosis.

Study description

Background summary

A high chloride concentration determined in sweat is the gold standard to confirm the diagnosis Cystic Fibrosis (CF). Validated methods for performing a sweat test are the Quantative Pilocarpine Iontophoresis (QPIT) method and the Macroduct. In young infants, for example neonates with a positive newborn screening test for CF, the sweat test often fails. This may lead to a diagnostic delay and a long stressful period for the parents. The Nanoduct is a new system for performing a sweat test, but this method is not yet validated as a diagnostic instrument.

Study objective

To determine the reliability and feasibility of the Nanoduct sweat test system compared to the gold standard tests QPIT and Macroduct.

Study design

A prospective comparing study te determine the failure rate of the Nanoduct versus the QPIT/ Macroduct.

Intervention

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

Study burden and risks

All infants will have to undergo two tests instead of one. The sweat test is not painful nor distressing. The risk for complications is practically absent,, the only risks reported are mild burns or skin irritation when the test is performed by non-skilled personnel or when the protocol is not followed. For the included children there is no benefit as we will rely on the results of the gold standard test.

Contacts

Public

RIVM

Postbus 1 3720 BA Bilthoven Nederland **Scientific** RIVM

Postbus 1

3720 BA Bilthoven

Nederland

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 < 2 months with a suspected diagnosis of Cystic Fibrosis. informed consent has been obtained

from the parents.

Exclusion criteria

Newborns with severe eczema or sepsis (sweat test results are not reliable). Infants with meconiumileus. Informed consent cannot be obtained.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Will not start

Enrollment: 330

Type: Anticipated

Ethics review

Not approved

Date: 26-06-2008

Application type: First submission

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 NL20953.000.08