# 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.

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|---|---|
| **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**
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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 < 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 |