# Children's Health Assessment and Molecular Pathogen Identification for Optimized Novel Sepsis therapy

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The aim of this study is to establish the accuracy of Molecular Culture for prediciting the outcome of the traditional blood culture.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56522

**Source**
ToetsingOnline

**Brief title**
CHAMPIONS

### Condition

- Bacterial infectious disorders

**Synonym**
blood poisoning, Sepsis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Inbiome, Amsterdam

## Intervention

**Keyword:** IS-pro, Molecular Culture, Neonatal sepsis

## Outcome measures

### Primary outcome

The diagnostic accuracy of the Molecular Culture technique for predicting the outcome of the current conventional blood culture

### Secondary outcome

The diagnostic accuracy of the Molecular Culture and of the current conventional blood culture for clinical sepsis, which will be defined in various ways.

Diagnostic accuracy of the molecular culture on blood sampled <72 hours post initiation of antibiotics to assess detectibility of bacteria in presence of antibiotics

# Study description

### Background summary

Babies and children have an increased risk of getting an infection with a bacteria in the bloodstream (sepsis). It is often difficult for the doctor to determine whether a child has an infection of the bloodstream, because the symptoms are often unclear and can also occur in children who are not sick. To determine whether there is an infection, a little blood is currently taken for a blood test (theblood culture) to investigate whether there is a bacteria in the blood. However, it often takes at least 36 hours before the results ofthis blood culture are available. That is why antibiotics are usually started immediately to treat the possible infection.

However, it often turns out that the blood culture is negative after 36 hours, which means that no bacteria have been found in theblood. Usually the antibiotics are then stopped because it turns out that there was no infection at all. There is currently no good test that can predict whether (newborn)

children have an infection or not. That is why too many children are currently wrongly receiving antibiotics. These antibiotics can damage the healthy bacteria in the intestines. There are many billions of 'beneficial bacteria' in theintestine. These play an important role in the digestion of food and protect against external infections. Antibiotics aim to kill bacteriathat cause inflammation or infection. Unfortunately, antibiotics also kill some of these beneficial bacteria. In addition, unnecessaryuse of antibiotics contributes to antibiotic resistance. The aim of this research is to investigate whether Molecular Culture, a PCR based test that can identify bacterial pathogens in bodily fluids within 4 hours, has greater accuracy than traditional culturing techniques for bacteria in blood. If proven, this could lead to faster identification or exclusion of sepsis in children.

### Study objective

The aim of this study is to establish the accuracy of Molecular Culture for prediciting the outcome of the traditional blood culture.

### Study design

Multicenter, prospective, observational cohort study

### Study burden and risks

There is no/minimal extra burden for participants. One or several extra tubes of blood will be sampled during a regular blood sampling for thisstudy.
There will be no direct benefits for participants, but future patients might benefit from this technique.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

## Inclusion criteria

• Undergoing collection of blood for a conventional blood culture for standard care
OR
Having undergone collection of blood for conventional blood culture for standard care in the past 72 hours

AND
Informed consent

## Exclusion criteria

None

# Study design

## Design

**Study type:** Observational invasive
Masking: Open (masking not used)

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|---|---|
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-03-2024 |
| Enrollment: | 1200 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 16-02-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-11-2024 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## 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 | NL84592.018.23 |