

# Specturi Device - Feasibility study

Published: 23-06-2016

Last updated: 04-07-2024

Clinical feasibility of the urine collection device, indicated by staff and parents.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Bone, calcium, magnesium and phosphorus metabolism disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON54632

### Source

ToetsingOnline

### Brief title

Specturi feasibility study

### Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

### Synonym

English disease, Rickets

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Capturin Distributie BV

**Source(s) of monetary or material Support:** Fonds Nuts OHRA;Friesland Campina (tegenwoordig Hero Kindervoeding;xx);TKI PPP Allowance HH,Hertog Hendrik BV,Scint B.V.

### Intervention

**Keyword:** collecting device, Prematurely born newborns, Rickets, urine

## Outcome measures

### Primary outcome

Clinical feasibility of the urine collection device, indicated by staff and parents

### Secondary outcome

Skin reactions and skin irritability

## Study description

### Background summary

On a daily basis many (prematurely born) newborns are subjected to different urine collecting techniques to study biochemical abnormalities. Neonatology nurses and pediatricians are looking for a better and less invasive manner to collect urine in these vulnerable patients. We hypothesise that the urine collecting device as presented in this protocol is less invasive and has good functional abilities to collect urine in these newborns

### Study objective

Clinical feasibility of the urine collection device, indicated by staff and parents.

### Study design

The study will be an open label, clinical feasibility study, of the urine collection device. During a period of 6 months, 30 feasibility tests will be performed. Every subject has a maximum of 3 tests.

### Study burden and risks

This study involves a negligible amount of risk to a very vulnerable group of test subjects, being neonates admitted to the neonatology unit of the department of pediatrics of the Rijnstate hospital.

## Contacts

### Public

Capturin Distributie BV

President Kennedylaan 100

Velp 6883 AZ

NL

### Scientific

Capturin Distributie BV

President Kennedylaan 100

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Newborns

Premature newborns (<37 weeks pregnancy)

### Inclusion criteria

Neonates admitted to the neonatology unit of the Maternity care department of Rijnstate Hospital and Radboud Hospital Nijmegen

Medical indication for urine testing using a urine collection device

Informed consent from parents

### Exclusion criteria

No informed consent

Defective skin in genital region

Three previous test in the same subject

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-01-2020

Enrollment: 10

Type: Actual

### Medical products/devices used

Generic name: Rachitis Collector Pad Device

Registration: No

## Ethics review

Approved WMO

Date: 23-06-2016

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 29-11-2016

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 02-08-2017

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	18-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	27-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	07-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	11-01-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	27-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	31-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	01-07-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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
ClinicalTrials.gov	NCT03105557
CCMO	NL55778.091.15