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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	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) newborn a 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

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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