Acute Kidney Injury in critically ill infants

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1. To assess reference values of a pre-defined set of biomarkers for AKI in *surgical* infants with normal kidney function.2. To determine the incidence of AKI in critically ill infants, according to pRIFLE criteria.3. To evaluate the sensitivity...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON38246

Source
ToetsingOnline

Brief title
AKI in critically ill infants

Condition

- Renal disorders (excl nephropathies)

Synonym
Acute Kidney Injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Sophia Stichting voor Wetenschappelijk Onderzoek (SSWO);projectnummer 633

Intervention

Keyword: Acute Kidney Injury, Child, Critically ill, New Biomarkers

Outcome measures

Primary outcome

1. To assess reference values of a pre-defined set of biomarkers for AKI in

surgical infants with normal kidney function.

2. To evaluate the sensitivity and specificity of these biomarkers in

predicting AKI as well as the incidence of AKI in critically ill infants.

Secondary outcome

None

Study description

Background summary

Critically ill children are at risk of developing AKI due to insufficient circulation. AKI has consequences for treatment. For example, dosage of drugs that are eliminated by the kidneys needs to be adjusted to avoid accumulation, and nephrotoxic drugs should be avoided.
The usual method to detect AKI, i.e. by serum creatinine level, provides for relatively late detection of kidney failure only. The introduction of this panel of biomarkers will enable earlier detection of AKI. Then, medical treatment can be adjusted earlier.

In the current study we propose to use the following biomarkers:
Serum Cystatin C
Serum Beta-Trace-Protein
Urine Neutrophil-Gelatinase-Associated-Lipocalin
Urine Interleukin-18
Urine Kidney Injury Molecule-1
Urine Fibroblast Growth Factor-2
Urine Metalloproteinase-2
Urine Vascular Endothelial Cell Growth Factor
Urine Epidermal Growth Factor
Finally, when other biomarkers for AKI emerge, we may include these in the analysis.

The samples will be transferred for biomarkers measurements of FGF-2, MMP-2, VEGF and EGF to the center for Molecular Physiology Research, Division of

Nephrology, Children*s National Medical Center (CNMC), Children*s Research Institute, Washington, District of Columbia, United States of America.

The different properties of the mentioned biomarkers emphasizes that a panel of biomarkers may be needed to demonstrate AKI.

Study objective

1. To assess reference values of a pre-defined set of biomarkers for AKI in *surgical* infants with normal kidney function.
2. To determine the incidence of AKI in critically ill infants, according to pRIFLE criteria.
3. To evaluate the sensitivity and specificity of these biomarkers in predicting AKI in critically ill infants

Study design

Prospective clinical observation trial executed in four hospitals:
ErasmusMC - Sophia Children's Hospital Rotterdam
UMC St. Radboud Nijmegen
Albert Schweitzer Ziekenhuis Dordrecht
Sint Fransiscus Gasthuis Rotterdam

Study burden and risks

The risks and burdens associated with this study are negligible. Blood samples are taken from an indwelling catheter already in place for clinical purposes or by a capillary punction which is considered to be a minimal invasive procedure. Urine samples will be collected by using a urine catheter or) or by a gauze in the patient*s diaper from which urine will be extracted. Bladder catherization is part of standard care in case of ECMO treatment or treatment of critically ill children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Age: Up to 12 months
- Group 1: - Patients admitted for minor surgical procedures with stable hemodynamics and normal kidney function: term up to 1 year of age
- Group 2: - Critical illness: mechanical ventilation
- Need for vasopressor drugs
- Group 3: - Critically ill patients with ECMO treatment
- Group 4: - Neonates admitted for minor surgical procedures with stable hemodynamics and normal kidney function: 32 up to 37 weeks of gestational age

Exclusion criteria

- No informed consent
- Pre-existent kidney disease or kidney anomaly on ultrasound
- Group 1 and 4: Use of known nephrotoxic drugs, like aminoglycosides
pRIFLE score showing AKI
- Group 1, 2, 3: Preterm birth
- Group 4: Preterm birth before 32 weeks of gestational age

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	390
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30981.078.10