

Alpha-1-microglobulin to diagnose acute pyelonephritis

Published: 07-02-2007

Last updated: 20-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON30689

Source

ToetsingOnline

Brief title

alpha-1-microglobulin

Condition

- Urinary tract signs and symptoms

Synonym

pyelonephritis

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis

Source(s) of monetary or material Support: eigen middelen amphia ziekenhuis

Intervention

Keyword: acute pyelonephritis, alpha-1-microglobulin, children, fever

Outcome measures

Primary outcome

We want to prove the diagnostic value of alpha-1-microglobulin/creatinine ratio in urine in comparison to the best diagnostic option at this moment to prove an APN, a DMSA-scan.

Secondary outcome

none

Study description

Background summary

At this moment it is not easy for a pediatrician to diagnose an acute pyelonephritis (APN). An APN is a serious problem, requesting accurate therapy and follow up. The pediatrician uses a couple of diagnostic options: his own clinical findings, urine-screening and sometimes, when he is not sure, a ⁹⁹Tc dimercaptosuccinic acid scan (DMSA-scan). The DMSA-scan seems to be the best diagnostic option, in comparison to histopathological finding, in case of an APN.

In a couple of non-prospective studies a protein called Alpha-1-microglobulin seems to be a good option to make an APN sure. The A1M concentration has to be measured out of the urine. The quantity is being expressed in mg/g creatinine in the urine. When there is a bacterial focus in the pyelum of the nephron, the ratio increases significantly. This ratio does not increase in case of a lower urinary tract infection nor it does when the inflammatory focus is situated outside the urinary tract. The measurement of A1M/creatinine is in comparison to other diagnostics cheap, quick and probably it has got enough power to make an APN sure or to exclude it.

Study objective

We want to prove whether the A1M/creatinine ratio in the urine is a good marker to diagnose an APN, or not. The study design has been made of a prospective observational cohort, controlled by a DMSA-scan.

Our aim is to use the A1M/creatinine marker in the future as a quick, cheap, good marker to diagnose an APN without an intervention. And to prevent the patient from invasive exams or prophylactic antibiotics.

Study design

In this study we are proving the diagnostic value of the A1M/creatinine ratio in urine in comparison to the DMSA-scan. When the urine has sedimental changes, the patient surely has a urinary tract infection; the inflammatory focus may be presented as an APN or a lower urinary tract infection (LUTI). A DMSA-scan will be performed in all patients with an abnormal urine sediment and fever. We will compare our results to normal urine sediment patients with fever or/and patients with abnormal urine sediment without fever. In these patients there won't be a DMSA-scan made. Two weeks after lowering fever we want to measure the A1M/creatinine ratio again in all patients included.

Study burden and risks

neglectable

Contacts

Public

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Scientific

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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)

Inclusion criteria

fever of unknown origine or with symptoms of the urinary tract

Exclusion criteria

preexistent nephropathy, hypertension, artery renalis stenosis, diabetes mellitus, sepsis, immunosuppressive drugs

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-02-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date: 07-02-2007

Application type: First submission

Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL14095.101.06