

Examination of Pyelonephritis In Children, with MRI.

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Primary objective:-To diagnose acute pyelonefritis with MRI in comparison with the reference standard: DMSA scanning.Secondary objectives:- To determine whether MR-diffusion weighted imaging (DWI) has additional value in the imaging of...

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

Summary

ID

NL-OMON34233

Source

ToetsingOnline

Brief title

The EPIC trial

Condition

- Renal disorders (excl nephropathies)

Synonym

kidney infection, pyelonephritis

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: Foreest medical school en externe financiering,Siemens

Intervention

Keyword: MRI, Paediatric, pyelonephritis

Outcome measures

Primary outcome

Pyelonephritis foci in renal parenchyma.

Secondary outcome

Renal scarring.

Study description

Background summary

Urinary tract infection (UTI) is a common and critical childhood disease which occurs in at least 8 % of all girls and 2 % of all boys.

UTI may lead to upper tract infection and acute pyelonephritis if prompt diagnosis and treatment are delayed. In later life this may then lead to hypertension and impaired renal function. Therefore acute pyelonephritis needs prompt diagnosis in order to start antibiotic therapy to prevent scar formation.

Although children with pyelonephritis tend to present with fever, flank pain and a positive urine culture, the diagnosis is usually difficult to make on clinical grounds, especially in young children. Thus there is the need to support or reject the diagnosis with radiological examination.

Currently the accepted reference standard for the diagnosis of acute pyelonephritis is DMSA scanning. Unfortunately there are some disadvantages to this technique. First of all, the need for an infusion needle and the exposure to ionising radiation.

MRI has the potential to diagnose pyelonephritis surpassing these disadvantages.

Study objective

Primary objective:

-To diagnose acute pyelonephritis with MRI in comparison with the reference standard: DMSA scanning.

Secondary objectives:

- To determine whether MR-diffusion weighted imaging (DWI) has additional value in the imaging of pyelonephritis.
- To determine whether MRI scanning can differentiate acute pyelonephritis from renal scarring

Study design

Level IIb study, validating cohort.

Study burden and risks

Burden

- Patients need to lie still, furthermore the MRI makes loud noises.

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)

Inclusion criteria

1. Patients from 0 to 18 years with:
Acute pyelonephritis, defined as a UTI * with a body temperature above 38 °C.
Suspicion of acute pyelonephritis, suggested by symptoms of a UTI and flank pain.
2. Outside the study setting, the patient would have received a DMSA scan
3. Patients, or a legal representative, must be able to give informed consent, and the consent must be obtained prior to the MR Imaging and DMSA scanning

Exclusion criteria

1. Previous diagnosis of pyelonephritis
2. All contra-indications for undergoing MRI.
3. A psychiatric, addictive, or any disorder that compromises the ability to give truly informed consent for participation in this study.

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): 04-04-2011

Enrollment: 80

Type: Actual

Ethics review

Approved WMO

Date:	06-12-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL32462.094.10