

Examination of Pyelonephritis In Children with magnetic resonance imaging (MRI)

Submission date 01/04/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/07/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/11/2012	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL32462.094.10

Study information

Scientific Title
Examination of Pyelonephritis In Children with magnetic resonance imaging (MRI): a cohort study

Acronym
EPIC

Study objectives

Magnetic resonance imaging (MRI) can be used as an alternative to dimercaptosuccinic acid (DMSA) for the diagnosis of pyelonephritis in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

METC Noord Holland approved on 30th November 2010, ref: NL32462.094.10

Primary study design

Observational

Study design

Validating cohort study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pyelonephritis

Interventions

MR-imaging is performed within 8 hours of the DMSA scan. MR examinations of the abdomen and pelvis are performed with the patient in supine position and with a body phased-array coil (better signal-to-noise ratio) on a 1.5-T system (Magnetom Avanto, Siemens, Erlangen, Germany). All MR examinations are performed using a set protocol. Single-shot images (if possible with breath-hold) are made to provide a motion-insensitive image, even in the presence of severe motion. The total examination time is less than 20 min for the MRI in total.

The parents can accompany the patient during the examination. If necessary a nurse from the paediatric department may also accompany the patient.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. The sensitivity, specificity, positive and negative predictive value and inter observer agreement of MRI in diagnosing acute pyelonephritis as compared to the reference standard.
 - 1.1. The MRI findings will be compared to the findings at imaging of the standard diagnostic work-up that preceded MRI. The diagnostic value of specific MRI characteristics for pyelonephritis will be calculated. The value of diffusion-weighted imaging (DWI) will be analysed.

Key secondary outcome(s)

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

Completion date

04/04/2013

Eligibility

Key inclusion criteria

1. Patients from 0 to 18 years, with:
 - 1.1. Acute pyelonephritis, defined as a urinary tract infection (UTI) with a body temperature above 38 °C
 - 1.2. Suspicion of acute pyelonephritis, suggested by symptoms of a UTI and flank pain
2. For young children (under the age of 1 year and in the pre-verbal phase) other clinical symptoms can suggest pyelonephritis. This is bacteriuria with either fever, vomitus, lethargia, anorexia, abdominal pain, pollakisuria or flank pain
3. Outside the study setting, the patient would have received a dimercaptosuccinic acid (DMSA) scan
4. 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 Years

Sex

All

Key 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

Date of first enrolment

04/04/2011

Date of final enrolment

04/04/2013

Locations

Countries of recruitment

Netherlands

Study participating centre
Wilhelminalaan 12
Amsterdam
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1800 AM

Sponsor information

Organisation
Foreest Medical School (Netherlands)

ROR
<https://ror.org/00bc64s87>

Funder(s)

Funder type
University/education

Funder Name
The Foreest institute (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration