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

Submission date	Recruitment status	[_] Prospectively registered
01/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2012	Urological and Genital Diseases	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Validating cohort study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
04/04/2011

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

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
80

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
Netherlands
1800 AM

Sponsor information

Organisation
Foreest Medical School (Netherlands)

Sponsor details
26 Juni Arcadialaan 14
Amsterdam
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1813 KN

Sponsor type
University/education

Website
http://www.foreestmedicalschool.nl

ROR
https://ror.org/00bc64s87

Funder(s)

Funder type
University/education

Funder Name
The Foreest institute (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration