ISRCTN98320102 https://doi.org/10.1186/ISRCTN98320102

Magnetic resonance imaging (MRI) fluoroscopy for imaging childhood vesicoureteric reflux

Submission date	Recruitment status	[_] Prospectively registered
07/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/07/2017	Surgery	

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
6149

Study information

Scientific Title
Magnetic resonance imaging (MRI) replacement of x-ray fluoroscopy in paediatric imaging: an investigation of vesicoureteric reflux

Study objectives
X-ray fluoroscopy is widely used for diagnosing suspected serious childhood abnormalities such as urinary tract abnormalities, despite the induced solid malignancy risk secondary to ionising radiation exposure. Magnetic resonance imaging (MRI) is considered safer than X-rays, but fluoroscopy-like MRI techniques have not yet been developed for paediatric applications, where the avoidance of ionising radiation would be of great benefit. Development requires the integration and adaptation of MR technologies to support the study of small children in the relatively hostile environment of an MR system, and evidence that similar results to X-ray fluoroscopy are achievable.

Aims:
1. To develop robust MR applications based on recently developed MR technology for childhood abnormalities of the renal tract (vesicoureteric reflux and posterior urethral valves).
2. To evaluate the technical and diagnostic performance of the MR technique by direct comparison with the established X-ray fluoroscopy based techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 3 Research Ethics Committee, 26/06/2008, ref: 08/H0306/39

Study design
Single-centre non-randomised observational diagnosis and validation of investigative process trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions
All patients volunteering for this study will undergo conventional XR fluoroscopy as per standard care, followed by an additional MRI examination. Data collection involves completion of demographic proformas, parent questionnaires, and real-time acquisition of radiological images which will be assessed and stored for retrospective analysis. The two examinations are expected to take place within 24 hours of each other. The conventional X-ray studies will be reported immediately following normal practice and allowing for clinical management and decision making. Both the XR and MRI studies will be reported for the presence/absence of posterior urethral ballooning during voiding and the presence and grade of any VUR using the conventional established grading scheme. In each case the person supervising and reporting the respective studies will not be aware of the results of the other investigation.

There is no follow-up as part of this study, but patients will be treated as per standard care on the basis of the results from their XR fluoroscopy examination.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The ability of the MR fluoroscopy examination to accurately detect:
1. Significant grade VUR likely to alter clinical management
2. The presence of posterior urethral ballooning

Assessed at the time of the intervention

Secondary outcome measures
Assessed at the time of the intervention:
1. Image quality
2. Artifacts

Overall study start date
01/09/2008

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. All children (usually boys) between the ages of 0 and 3 years referred for direct micturating cysto-urethrography (MCUG)
2. All children with hydronephrosis diagnosed antenatally on foetal ultrasound
3. Age range: 0 days - 3 years, male and female

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
3 Years

Sex
Both

Target number of participants
Planned sample size: 50

Key exclusion criteria
1. Usual MR exclusion criteria will apply, but are highly unlikely in this age group. The include pregnancy, claustrophobia, cardiac pacemakers, metallic implants, cardiac defibrillator implants, aneurysm clips or metallic heart valves, and cochlear or inner ear implants. These exclusion criteria clearly apply to all people within the vicinity of the MRI scanner, and therefore apply equally to the parents/guardians in this study.
2. Previous reaction to the relevant x-ray or MRI contrast medium (including gadolinium)
3. Congenital abnormalities that make X-ray fluoroscopy of MR fluoroscopy impractical

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Wendy Phillips (wendyphillips@addenbrookes.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No