

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

<b>Submission date</b> 07/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/07/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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**  
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

## **Study type(s)**

Diagnostic

## **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(s)**

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

**Key secondary outcome(s)**

Assessed at the time of the intervention:

1. Image quality
2. Artifacts

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

0 years

**Upper age limit**

3 years

**Sex**

All

**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 or MR fluoroscopy impractical

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/09/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Addenbrookes Hospital**

Cambridge

United Kingdom

CB2 0QQ

## Sponsor information

**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

**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

### 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?
<a href="#">Results article</a>	results	01/03/2013		Yes	No