

Magnetic resonance imaging (MRI) fluoroscopy for imaging childhood gastrointestinal malrotation

Submission date 07/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/07/2017	Condition category 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
6144; G0800411

Study information

Scientific Title

Magnetic resonance imaging (MRI) replacement of x-ray fluoroscopy in paediatric imaging: an investigation of gastrointestinal malrotation

Study objectives

The aim of this study is to develop rapid magnetic resonance imaging (MRI) techniques which will replace X-ray fluoroscopy methodology for diagnostic imaging in children with suspected gastrointestinal abnormalities (e.g., gut malrotation).

This project has two parts:

1. The aim is to optimise the MRI environment for small children, including patient handling, communication, nursing and parental support requirements, and refinement of MR protocols, with direct parent feedback.
2. A diagnostic performance trial will then be conducted, a non-randomised feasibility trial comparing the established X-ray investigation with the optimised MR investigation in children with suspected gut abnormalities, to ensure that MRI is as good, if not better than, X-ray testing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 3 Research Ethics Committee, 15/04/2008, ref: 08/H0306/7

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

Interventions

All patients volunteering for this study will undergo the conventional XR fluoroscopy examination as per standard practice, followed by an additional MRI examination.

The diagnosis of the XR test will be known, in order to select the patients most appropriate for MR examination. However, the MRI examination will be reported by a radiologist blinded to the diagnosis made on X-ray. As the presence or absence of gut malrotation is a stable diagnosis, the confirmation of its presence on the X-ray test is unlikely to affect the MRI test.

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 on the same day. The conventional X-ray studies will be reported immediately following normal practice to allow for immediate

clinical management. In each case the person supervising and reporting the respective studies will not be aware of the results of the other investigation.

Upper gastrointestinal studies will be reported for the presence/absence of the duodeno-jejunal flexure in the correct anatomical location, and for any other duodenal or jejunal abnormalities.

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

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Can a technique using magnetic resonance MR fluoroscopy be developed to replace the conventional X-ray fluoroscopy methodology? All outcomes will be assessed at the time of the intervention.

Key secondary outcome(s)

To demonstrate the feasibility of magnetic resonance imaging for this type of paediatric imaging, including an assessment of its technical and diagnostic performance, by direct comparison with the established X-ray fluoroscopy based techniques. After each participant has their MRI scan, the results will be compared with those obtained with the standard X-ray fluoroscopy technique, and scored for sensitivity and accuracy in diagnosing gut malrotation. All outcomes will be assessed at the time of the intervention.

Completion date

01/09/2011

Eligibility

Key inclusion criteria

1. All children between the ages of 0 and 6 years referred for an upper gut XRF contrast study for suspected upper intestinal obstruction, i.e., malrotation
2. Age range: 1 day to 6 years, male and female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

0 years

Upper age limit

6 years

Sex

All

Key exclusion criteria

1. Usual MR exclusion criteria will apply, but are highly unlikely in this young age group. They 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 would apply to all people within the vicinity of the MRI scanner, e.g., the parents/guardians in this study.
2. Previous reaction to the relevant X-ray or MRI contrast media (including gadolinium)
3. Congenital abnormalities that make X-ray fluoroscopy or MR fluoroscopy impractical

Date of first enrolment

01/11/2008

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

Research council

Funder Name

Medical Research Council Clinical Research Training Fellowship (MRC CRTF) (UK) - Royal College of Radiologists (ref: G0800411)

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?
Results article	results	22/09/2014		Yes	No