ISRCTN55042368 https://doi.org/10.1186/ISRCTN55042368

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Wendy Phillips

Contact details
Radiology, Box 162
Hills Road
Cambridge
United Kingdom
CB2 0QQ
-
wendyphillips@addenbrookes.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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: 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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/11/2008

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

Age group
Child

Lower age limit
0 Years

Upper age limit
6 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 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
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
Research council

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

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	22/09/2014		Yes	No