

How does preoperative fasting affect the success rate of magnetic resonance imaging in sedated infants?

Submission date 18/12/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2020	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Small children often need sedation or anaesthesia to lie still during magnetic resonance imaging (MRI) procedures. One common sedative used for MRI scanning is dexmedetomidine, which may be nebulised (sprayed) into the nose. One problem with this type of sedation is that the child is easily woken up by any painful stimuli, noise or even other factors such as hunger or thirst. If the child wakes up during MRI scanning, the procedure has to start over or even be cancelled.

Traditionally, children are required to fast 4 hours for breast milk and 6 hours for other food before anaesthesia and deep sedation. Very young children (neonates) may often undergo MRI scanning without sedation if they are well fed prior to the procedure. Infants may also benefit from feeding before the procedure.

The study aims to investigate if there are fewer problems with movement if the young child is fed within an hour prior to the MRI.

Who can participate?

Children < 3 years old scheduled for short (<45 minutes) MRI procedures with dexmedetomidine sedation may be included.

What does the study involve?

In our department, they are routinely fasted for at least 4 hours prior to MRI. They are randomised to keep fasting until the procedure is done or to be fed about one hour prior to the scanning. 45 minutes prior to the procedure, dexmedetomidine is sprayed into the nose. We will record if the MRI scanning has to be interrupted or cancelled due to movements or other problems. In addition, we will ask the parents of children who are bottle-fed to record the time and volume of the feeding. Then we will add scanning of the stomach to the MRI protocol, with the aim of determining the residual content in the stomach, and thereby the speed of gastric emptying.

What are the possible benefits and risks of participating?

Possible benefits are less hunger and discomfort in children who are randomised to be fed before the procedure, and reduced risk of prolonging or aborting the MRI scan procedure due to

problems with children waking up or moving during scanning.
Possible risks are children vomiting while in the MRI scanner, leading to aborted procedure or breathing problems.

Where is the study run from?
Uppsala University Hospital, Sweden

When is the study starting and how long is it expected to run for?
January 2020 to December 2021

Who is funding the study?
Uppsala University Hospital, Sweden

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

MRI-scanning of infants facilitated by dexmedetomidine sedation. Can reduction of pre-procedure fasting reduce the risk of movement artifacts?

Acronym

MRFASTA

Study objectives

Allowing infants to feed within an hour of MRI scanning reduces the incidence of movements leading to artifacts or prolonged procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/08/2018, Uppsala Regional Ethics Committee (The Swedish Ethics Review Authority, Box 2110, 750 02 Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2019-04484

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet available in Swedish.

Health condition(s) or problem(s) studied

Infants undergoing MRI scanning with dexmedetomidine sedation

Interventions

Children < 3 years old scheduled for short (<45 minutes) MRI procedures with dexmedetomidine sedation may be included. In the researchers' department, children are routinely fasted for at least 4 hours prior to MRI. They are randomised to keep fasting until the procedure is done or to be fed about one hour prior to the scanning. 45 minutes prior to the procedure, dexmedetomidine is sprayed into the nose. The researchers will record if the MRI scanning has to be interrupted or cancelled due to movements or other problems. In addition, they will ask the parents of children who are bottle-fed to record the time and volume of the feeding. Then they will add scanning of the stomach to the MRI protocol, with the aim of determining the residual content in the stomach, and thereby the speed of gastric emptying.

Randomisation:

A randomisation list is produced in MS Excel, and the outcome is transferred to sealed envelopes that are opened when each patient has been included after written informed consent from the parents.

Intervention Type

Procedure/Surgery

Primary outcome measure

MRI scan outcome (with or without movement artefacts) when the patient is moved from the MRI suite after the scanning procedure

Secondary outcome measures

1. Duration of MRI scanning procedure, the time from the patient is laid onto the MRI scanner bed until the patient is taken off the bed after the completed scan
2. Incidence of movements during the procedure, the number of times the MRI scanning is stopped due to observed movements of the patients or movement artefacts on the MRI scan preview. Each movement event is recorded on the CRF when it occurs and summed at the end of the procedure
3. Complications of the procedure
4. The volume of residual gastric volume content after bottle feeding 1-4 hours prior to scanning is measured by delineating the gastric mucosa on adjacent MRI images covering the full extent of the stomach and calculating the volume in millilitres by summing the resulting voxels. An estimate of gastric emptying rate is calculated by integrating the sets of ingested volume VOIs subtracted by the residual volume vs time between ingestion and the start of scanning of the stomach

Overall study start date

01/08/2018

Completion date

31/12/2021

Eligibility**Key inclusion criteria**

Infants planned for an MRI scan

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Age < 3 months
2. Age > 36 months
3. Gastro-esophageal reflux disease
4. Respiratory disease such as bronchopulmonary dysplasia, requiring oxygen therapy or CPAP
5. Congenital heart disease with cyanosis or myocardial dysfunction
6. MRI protocol planned duration > 45 minutes

Date of first enrolment

15/01/2020

Date of final enrolment

01/12/2021

Locations**Countries of recruitment**

Sweden

Study participating centre

Uppsala University hospital

Sjukhusvägen 1

Uppsala

Sweden

75185

Sponsor information**Organisation**

Uppsala University Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.akademiska.se/>

ROR

<https://ror.org/01apvbh93>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Uppsala University Hospital

Results and Publications

Publication and dissemination plan

The researchers plan to publish their results in a peer-reviewed scientific journal and present them at pediatric anaesthesia meetings during 2021.

Intention to publish date

01/06/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request