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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

Registration date
15/01/2020

Overall study status
Completed

Last Edited
10/12/2020

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Sponsor information

Organisation
Uppsala University Hospital

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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