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Neck collar for pediatric MRI sedation

Submission date	Recruitment status	[ ] Prospectively registered
24/02/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/04/2014	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Children require deep sedation when undergoing magnetic resonance imaging (MRI) scans. General anesthetics such as propofol cause airway narrowing and, in some cases, complete blockage of the airway. When you lose consciousness your head moves spontaneously, obstructing the airway. A device such as a neck support collar may help keep the airway open during sedation. The aim of this study is to assess the effect of a soft neck collar on the airway using an MRI scan.

Who can participate?
Patients aged from 2 to 4 years scheduled for an MRI scan of the brain.

What does the study involve?
Patients were sedated with propofol and underwent MRI scanning of the neck region. The procedure was carried out twice, first with the patients head in a neutral position on the MRI table, then with the patient wearing a soft neck collar.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Alexandria Faculty of Medicine (Egypt).

When is the study starting and how long is it expected to run for?
The study ran from December 2012 to December 2013.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
0301334

Study information

Scientific Title
Effect of neck collar on upper airway size in children sedated with propofol during magnetic resonance imaging

Study objectives
Assess the effect of a soft neck collar application in children sedated with propofol on the upper airway size and patency using magnetic resonance imaging.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Alexandria Main University Hospitals, 16/6/2011, IRB NO: 00007555-FWA NO:00015712

Study design
Prospective randomized single-blind cohort study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Pediatric MRI sedation

Interventions
Patients were sedated with propofol 1 mg.kg-1, then 50-100 µg.kg-1.min-1. Magnetic resonance images of the neck region, from skull-base down to the subglottic region, were obtained using a dedicated head-neck coil. A three-plane gradient echo scout view was acquired to visualize the gross anatomic details and help to plane for our main sequence, a T1 3D FFE axial sequence extending from the nasopharyngeal roof down to the subglottic region. The sequence was done before and after application of the neck collar. The first head position was determined by MRI to be neutral. The soft neck collar was then applied, maintaining neck extension.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Upper airway size measured during the MRI procedure

Key secondary outcome(s))
Incidence and frequency of complications measured during the procedure and until the patient is fully awake and discharged

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Patients scheduled for magnetic resonance imaging of the brain
2. Age from 2 to 4 years
3. ASA class I III

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
4 years

Sex

All

Key exclusion criteria
Any patient with hydrocephalus, tonsillitis and upper or lower respiratory disease

Date of first enrolment
01/12/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Egypt

Study participating centre
Alnasr street
Alexandria
Egypt
21615

Sponsor information

Organisation
Alexandria Faculty of Medicine (Egypt)

ROR
https://ror.org/00mzz1w90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Egypt)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes