

Neck collar for pediatric MRI sedation

Submission date 24/02/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2014	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

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

Contact name

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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