ISRCTN67090623 https://doi.org/10.1186/ISRCTN67090623

Neck collar for pediatric MRI sedation

Submission date
24/02/2014

Recruitment status
No longer recruiting

Registration date
11/04/2014

Overall study status
Completed

Last Edited
11/04/2014

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Moustafa Abdelaziz Moustafa
m.3abdelaziz@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Moustafa A. Moustafa

Contact details
Alnasr street
Smouha
Alboroug Buildings
Building 5
Flat 701
Alexandria
Egypt
21615
+20 (0) 1222373407
m.3abdelaziz@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Upper airway size measured during the MRI procedure

Secondary outcome measures
Incidence and frequency of complications measured during the procedure and until the patient is fully awake and discharged

Overall study start date
01/12/2012

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

Age group
Child

Lower age limit
2 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Champelion street
Azarita
Alexandria
Egypt
21256
+20 (0) 1287740750
alexmedethics@yahoo.com

Sponsor type
University/education

Website
http://www.alexu.edu.eg/

ROR
https://ror.org/00mzz1w90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Egypt)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration