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Effects of tramadol and dexmedetomidine on recovery in pediatric patients undergoing adenotonsillectomy

Submission date
14/07/2016

Recruitment status
No longer recruiting

Registration date
25/07/2016

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
An adenotonsillectomy is a common surgical procedure in which the small lumps of tissue at the back of the throat and nose (tonsils and adenoids) are removed. The tonsils and adenoids are part of the immune system they are not essential, and their removal does not damage the immune system in any way. The procedures are very simple and safe, and one of the most common complications is the agitation the child feels when they wake up from general anesthesia (being put to sleep for the operation). This puts a child at risk of hurting themselves, a longer stay in hospital, extra nursing care requirements, the family not being happy with the treatment and increased costs. In order to prevent this problem, giving extra medications as well as the general anesthesia is the standard approach. The aim of this study is to compare the effects of two commonly used drugs on agitation upon waking from general anesthesia (emergence agitation).

Who can participate?
Patients aged between 2-12 years who are having their tonsils and adenoids removed.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given dexmedetomidine (a sedative) mixed with normal saline (salt water) through a drip over a 10 minute period. Those in the second group receive tramadol (a pain-reliever) mixed with normal saline (salt water) through a drip over a 10 minute period. Participants in both groups are put to sleep for their surgery the same way and have their vital signs (such as heart rate, breathing and blood pressure) measured throughout surgery. Participants in both groups are then observed by clinical staff in the recovery area for an hour after their surgery to look for signs of emergence agitation.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in this study.

Where is the study run from?
Gazi University, Medical Faculty (Turkey)

When is the study starting and how long is it expected to run for?
January 2011 to January 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Andrew Hayward
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Contact information

Type(s)
Scientific

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Protocol serial number
EUEC-2011/135

Study information

Scientific Title
Tramadol vs dexmedetomidine for emergence reaction control in pediatric patients undergoing adenotonsillectomy with sevoflurane anesthesia: Prospective randomised controlled clinical study

Study objectives
The aim of this study is to evaluate the hypothesis that tramadol would control emergence agitation of sevoflurane as efficient as dexmedetomidine in pediatric patients undergoing adenotonsillectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erciyes University Research Ethics Committee, 01/03/2011, ref: 2011/135

Study design
Prospective single-centre randomised parallel trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postoperative pain after adenotonsillectomy

Interventions
Patients are randomised to one of two groups according to a computer generated random numbers table.

Group 1: After intubation, patients receive 1 µg/kg dexmedetomidine diluted in saline (2 ml of dexmedetomidine and 8 ml of saline) administered as a single IV dose over a 10 minute period.
Group 2: After intubation, patients receive 2 mg/kg tramadol diluted in saline 4 ml of tramadol and 6 ml of saline) administered as a single IV dose over a 10 minute period.

Standard anesthesia monitoring includes electrocardiogram, noninvasive blood pressure, pulse oximetry, and inspiratory and expiratory gas concentrations are applied to all the patients in both group during the surgery. Heart rate (HR), mean arterial pressure (MAP), peripheral oxygen saturation (SpO2), and minimum alveolar concentration (MAC) are also recorded before induction (baseline), at induction and every 5 minutes after induction during the procedure. After the end of the procedure at the post anesthesia care unit (PACU) the intensity of pain is assessed using a modified Hannallah pain score and observational pain score (OPS), pediatric anesthesia emergence delirium (PAED) scale, Ramsay sedation score (RSS). HR, MAP, SpO2 are measured and recorded on arrival to PACU and 5, 10, 15, 30, 45, 60 minutes after arrival to PACU. Any adverse effects such as vomiting, airway obstruction, laryngospasm or bronchospasm are also recorded.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
1. Tramadol 2. Dexmedetomidine

Primary outcome(s)

Pain intensity is assessed using a modified Hannallah pain score and observational pain score (OPS), pediatric anesthesia emergence delirium (PAED) scale, Ramsay sedation score (RSS) on arrival to PACU and 5, 10, 15, 30, 45, 60 minutes after arrival to PACU.

Key secondary outcome(s))
1. Heart rate is measured before induction (baseline), at induction and every 5 minutes after induction during the procedure
2. Mean arterial pressure is meaured before induction (baseline), at induction and every 5 minutes after induction during the procedure
3. Adverse events are monitored through clinical observations on arrival to PACU and 5, 10, 15, 30, 45, 60 minutes after arrival to PACU

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Patients ASA physical status I-II
2. Aged between 2 and 12
3. Undergoing adenotonsillectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
12 years

Sex
All

Total final enrolment
77

Key exclusion criteria
1. Developmental delay
2. Cardiac disorder
3. Psychological disorder
3. Epilepsy
4. Allergy to study medications

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
Gazi University, Medical Faculty
Anesthesiology Department
Ankara
Türkiye
06510

Sponsor information

Organisation
Gazi university, Medical Faculty

ROR
https://ror.org/054xkpr46

Funder(s)

Funder type
University/education

Funder Name
Gazi University, Medical faculty

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/03/2017	09/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes