Effect of mivacurium 200 and 250 mg/kg in children aged 6 months to 2 years (Eficacia del Mivacurium administrado a dosis de 200 y 205 µg/kg en niños de 6 meses a dos años de edad)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
03/10/2001		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/10/2001	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/09/2007	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr AA Nava-Ocampo

Contact details

Unit of Medical Research in Pharmacology Centro Médico Nacional Mexico City Mexico 03020 navaocampo_aa@yahoo.com

Additional identifiers

Protocol serial number HIM 97/011

Study information

Scientific Title

Study objectives

Patients undergoing an elective surgery of a planned duration not longer than 1 hour while requiring tracheal intubation during the procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anesthesia in children 6-24 months

Interventions

Patients randomly received an intravenous (iv) bolus dose of mivacurium 200 or 250 mg/kg. Isoflurane was administered to maintain anesthetic level during the surgical procedure. The times to onset of action and to spontaneous recovery of neuromuscular function were compared between groups. The area under-the-curve of the Heart Rate (HR), Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) were also compared between groups.

Ancillary analyses: In every group, the HR and SBP and DBP data obtained 5 min after mivacurium was administered were compared to their respective baseline values. In order to evaluate the effect of age and weight into onset and recovery times (data from all children), a single linear regression analysis (y = mx + b) was performed between each of the onset and recovery times as the dependent or explained variable and age or weight as the independent variable.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mivacurium

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/01/2001

Eligibility

Key inclusion criteria

- 1. Children aged 6 to 24 months
- 2. Low surgical risk (American Society of Anesthesiologists [ASA] grade I)
- 3. Suffering any ophthalmic, oto-rhynologic, plastic or orthopaedic disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

24 months

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

01/01/2001

Locations

Countries of recruitment

Mexico

Study participating centre

Unit of Medical Research in Pharmacology

Mexico City Mexico 03020

Sponsor information

Organisation

Federico Gomez Infant Hospital of Mexico (Hospital Infantil de Mexico Federico Gomez) (Mexico)

ROR

https://ror.org/00nzavp26

Funder(s)

Funder type

Research organisation

Funder Name

Fund to Encourage Research of the Mexican Institute of Social Security (Fondo de Fomento a la Investigacion of the Instituto Mexicano del Seguro Social) (Mexico) (grant ref: FP0038/988)

Funder Name

Secretariat of Public Education - National Council of Science and Technology (Secretraria de Educacion Publica - Consejo Nacional de Ciencia y Tecnologia [SEP-CONACyT]) (Mexico) (grant ref: 30591-M)

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?
Results article	Results	01/01/2001		Yes	No