

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 03/10/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/10/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/09/2007	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

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

Age group

Child

Lower age limit

6 Months

Upper age limit

24 Months

Sex

Both

Target number of participants

24

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)

Sponsor details

Subdireccion de Investigacion

Dr. Marquez 162

Colonia Doctores

Mexico DF

Mexico

CP06720

Sponsor type

Hospital/treatment centre

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/01/2001		Yes	No