

# 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)

<b>Submission date</b> 03/10/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/10/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2007	<b>Condition category</b> 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?
<a href="#">Results article</a>	Results	01/01/2001		Yes	No