ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID:	CINI-AD-20180808
Brief Title:	ED50 of Cis-atracurium for Laryngeal Mask Incubation in General Anesthesia
Official Title:	ED50 of Cis-atracurium for Laryngeal Mask Incubation in General Anesthesia During Urology Surgery
Secondary IDs:	

Study Status

Record Verification:	May 2019
Overall Status:	Recruiting
Study Start:	March 5, 2019 [Actual]
Primary Completion:	July 30, 2019 [Anticipated]
Study Completion:	July 30, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	China International Neuroscience Institution
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2018-XW-AD38 Board Name: Medical Ethics Committee of Xuanwu Hospital Board Affiliation: Xuanwu hospital Phone: 83198676 Email: w_tl5595@yahoo.com Address: 45 Changchun street, Xicheng district, Beijing, China
Data Monitoring:	

Study Description

Brief Summary:

1. The muscle relaxants can improve the conditions of laryngeal mask incubation and reduce the related complications (such as laryngeal spasm and postoperative throat pain)
2. The dosages of muscle relaxants used in various researches vary greatly.
3. We are planning use the most classical method for determining the ED50 or half effective concentration of cis-atracurium using sequential method, which is also called " up and down method" and " ladder method".

Detailed Description: The concordance of the current research is that muscle relaxants can improve the conditions of laryngeal mask incubation and reduce the related complications (such as laryngeal spasm and postoperative throat pain) of laryngeal mask incubation. It is necessary to use muscle relaxants in laryngeal mask incubation under non-special circumstances. However, the dosages of muscle relaxants used in various researches vary greatly of normal endotracheal intubation. Previous studies have shown that the amount of muscle relaxant required for laryngeal mask intubation is smaller than that required for endotracheal intubation. Although the dosage of muscle relaxant required for tracheal intubation can ensure the smooth insertion of laryngeal mask airway, laryngeal mask airway is mostly used for short surgery, which is prone to postoperative muscle relaxation residue and prolongs the recovery. We planning use the most classical method for determining the ED50 or half effective concentration of cis-atracurium using sequential method, which is also called " up and down method" and " ladder method".

Conditions

Conditions: Urologic Diseases

Keywords:

Study Design

Study Type: Observational [Patient Registry]

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 35 [Anticipated]

Number of Groups/Cohorts: 6

Target Follow-Up Duration: 1 Days

Groups and Interventions

Groups/Cohorts	Interventions
0.15mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names:

Groups/Cohorts	Interventions
of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.	• muscle relaxants
0.1mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. 0.15/1.5=0.1 (If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.)	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names: • muscle relaxants
0.07mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. 0.1/1.5=0.0667 (If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.)	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names: • muscle relaxants
0.05mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. 0.07/1.5=0.0466(If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.)	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names: • muscle relaxants
0.03mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. 0.05/1.5=0.0333 (If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.)	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names: • muscle relaxants
0.02mg/ kg group Administration method of cis-atracurium: the dose of the first patient is 0.15 mg / kg, and the ratio between adjacent doses is 1.5. 0.03/1.5=0.02(If the laryngeal mask insertion condition of this patient is satisfactory, the next patient will use the lower dose. If the laryngeal mask insertion condition of this patient is not satisfactory, the next patient will use a higher dose. Starting from the first case of dissatisfaction, the number of observation units is counted. Dissatisfaction - satisfaction occurs at 7 exchange points and then the test ends.)	Drug: Cis-atracurium Different concentration of cis-atracurium Other Names: • muscle relaxants

Outcome Measures

Primary Outcome Measure:

1. Laryngeal mask insertion conditions(satisfactory/unsatisfactory)
   The evaluation criteria of laryngeal mask insertion conditions are based on siva lingam's six-point three-level table, which is evaluated from the following six aspects: the degree of mouth opening, difficulty in laryngeal mask insertion, cough, retch, laryngeal spasm, and body movement. Each item is divided into 3, 2 and 1 points according to the

degree of severity, with a full score of 18 points, 16 points and above being satisfactory, and 16 points and below being unsatisfactory.

[Time Frame: through study completion, an average of 1 day]

Eligibility

Study Population: patients in Xuanwu Hospital for elective short urological surgery are selected. One day before surgery, visitors recorded basic information such as the patient's sex, age, BMI, ASA grade in the ward, carried out airway evaluation, and recorded the mouth opening to make sure they can be included

Sampling Method: Probability Sample

Minimum Age: 25 Years

Maximum Age: 75 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. ASA #~#level;
2. BMI18.5-30#
3. Those who intend to undergo short urological surgery (operation time < 1h);
4. Age 25~75 years
5. Estimated amount of bleeding < 5ml / kg.

Exclusion Criteria:

1. Neuromuscular diseases or metabolic diseases;
2. Preoperative complicated with water and electrolytes disorders (such as hypokalemia and hypocalcemia);
3. Serious hepatic and renal insufficiency and serious heart and lung diseases;
4. Predictable difficult airway;
5. Take drugs (such as aminoglycoside, polymyxin, phenytoin sodium, carbamazepine, etc.) that affect the nerve-muscle transmission function or the efficacy of muscle relaxants before surgery;
6. Muscle relaxation drug allergy;
7. Previous history of alcoholism or drug abuse.

Contacts/Locations

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