Brief Title: Hydroxyzine Dihydrochloride Premedication is a Necessity for Strabismus Surgery

Hydroxyzine Dihydrochloride Premedication is a Necessity for Pediatric Patients Undergoing Strabismus Surgery; An Observational Clinical Trial Controlled With Midazolam

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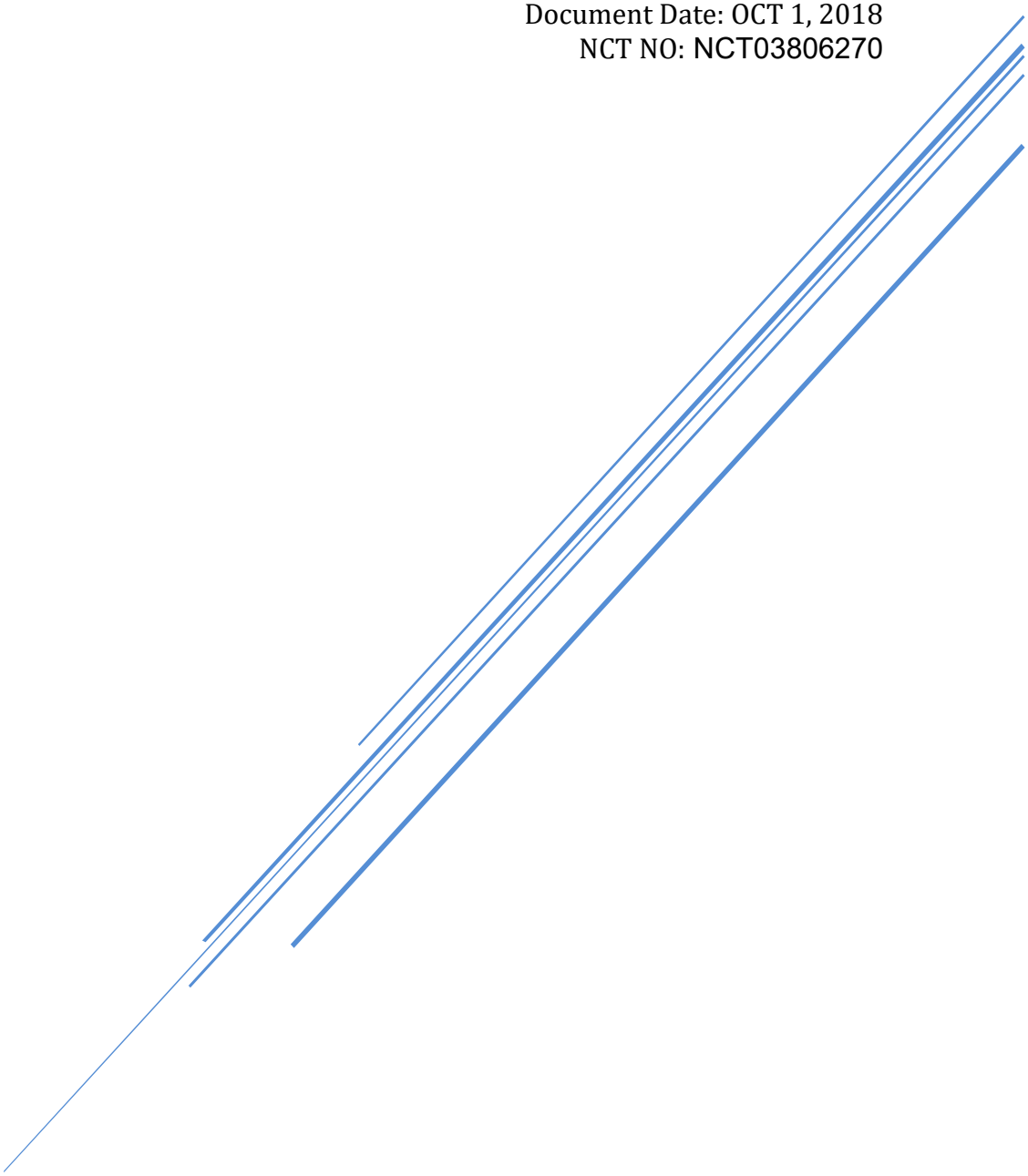

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Participant Code:

Study Protocol

1

The observational study named "Hydroxyzine Dihydrochloride Premedication is a Necessity for Pediatric Patients Undergoing Strabismus Surgery; An Observational Clinical Trial Controlled With Midazolam" will be done in Yeditepe University Hospital and Yeditepe University Eye Center. Seventy-five pediatric patients between one and ten years of age are planned to be included to the study who are planned to be scheduled for strabismus surgery.

Inclusion Criteria:

- Strabismus, surgery needed
- Esotropia, surgery needed

Exclusion Criteria:

- Chronic disease
- Arrhythmia
- Glaucoma(narrow-angle)

After having the oral and written consent form from the patients and their parents following data will be recorded.

Premedication

The anesthesiology doctor of the patient orders oral premedication for sedation before surgery. Premedication ordered and utilized will be seen and recorded by the investigator after the strabismus surgery from the written data in the patient's file, retrospectively. Therefore the patients will be grouped after the statistical data were recorded observationally in the operation theatre during the strabismus surgery.

The statistical data planned to be recorded in the operation theatre are; Ramsay Sedation score before surgery starts, ocular muscle name which traction performed, Heart Rate 1, Heart Rate 2 and Heart Rate 3, OCR occurrence, OCR treatment.

Heart Rate-1 The lowest heart rate observed from EKG monitorization at the "time-out" after the anesthesia induction in one minute time.just before the surgery starts. Heart rate-1 is a data, not an assessing change, which is recoded during the "time-out".

Heart Rate-2 The heart rate observed from EKG monitorization at the time operator warns the investigator just before the traction of every orbital muscle.

Heart Rate-3 The lowest heart rate observed from EKG monitorization, after every orbital muscle traction within 120 seconds.

Participant Code:

Ramsay sedation scale

Score	Response
1	Anxious or restless or both
2	Cooperative, orientated and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

HR: Heart Rate

HR(1) After Anesthesia induction
HR(2) Before traction performed to an ocular muscle
HR(3) After traction to an ocular muscle

OCR definition

1) HR (3), less than 20 % of HR (2)
2) Arrhythmia or asystole occurrence after traction of an ocular muscle

OCR treatment

1) to stop traction for a while
2) Atropine sulfate treatment ordered by the anesthesiology doctor of the patient regarding no HR response to the treatment number 1 above
3) Cardiac resuscitation regarding asystole or defibrillation regarding

Participant Code:

Participant Data in the operation theatre Form

Gender:
Age:
Height:
Weight:

Ramsay Sedation score (Tick in the parenthesis)

1( ) 2( ) 3( ) 4( ) 5( ) 6( )..

Perioperative data

Name of the Ocular muscle traction performed:.....
HR 1: ...../dk
HR 2: ..... /dk
HR 3: ...../dk

If more than one

Name of the Ocular muscle traction performed:.....
HR 1: ...../dk
HR 2: ..... /dk
HR 3: ...../dk

If more than two fill another form with the same participant code

OCR: occurred ( ) / not occurred ( )

If occurred;.

Ocular muscle name :
HR(2)-rate/minute :
HR(3) rate/minute :
Treatment number :

If occurred in more than one muscle;

Ocular muscle name :
HR(2)-rate/minute :
HR(3) rate/minute :
Treatment number :

Participant Code:

<u>If occurred in more than two muscle fill another form with the same participant code</u>

Premedication ordered and utilized to the participant

<u>Group 1 ( )</u> PO Midazolam (0,5 mg/kg) only

<u>Group 2</u> ( ) PO Midazolam (0,5 mg/kg) and Hydroxyzine Dihydrocloride (0,5mg/kg)

<u>Group 3.</u> ( ) PO Midazolam (0,5 mg/kg) and Hydroxyzine Dihydrocloride (1mg/kg)

After 36 participants
The participants will be grouped related to the premedication utilized to them.
There are three kinds of oral premedication are known to be ordered in the Yeditepe University hospital and in the Yeditepe University Eye Clinic according to our knowledge. If there is any other premedication (IV or IM) ordered or utilized to the patients, those will not be included in the study.

After reaching the same participant number in each group post hoc test (Tukey) will be performed and if more than one group comparison is calculated to be significantly different, the study will be stopped.
If not, the study will be stopped after reaching the calculated participant number 75 according to the power analysis done.