Postoperative Pain Management in Rhinoplasty: A Randomized Controlled Trial

Study Protocol

NCT03584152

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Title of the Study:

Postoperative Pain Management in Rhinoplasty: A Randomized Controlled Trial

Background:

In light of the increasing opioid abuse and addiction in the United States, there is a growing need to carefully monitor physician prescribed pain medications especially opioids, after outpatient surgery to reduce its misuse.

Purpose:

The purpose of this proposed study is twofold:

1) To explore the utility of pain medications other than opioids for adequate postoperative pain management specifically in rhinoplasty.

2) To explore the possibility of reducing the dosage or the number of prescribed opioid drugs from the current standard of prescribing opioid medications for five days after rhinoplasty.

Study Population:

Patients who are over the age of 18 years, undergoing functional, cosmetic or combined rhinoplasty procedures.

Study Design:

Randomized, double-blind controlled trial

Study Outcomes:

The primary outcome of interest is the assessment of intensity of postoperative pain experienced by patients scored on a visual analog scale (VAS) of 0-10 points (0- no pain and 10- most severe pain).

Additionally, the study will also seek to track:

1) The total number of pills each patient consumes from the prescribed 5-day regimen.

2) Any associated side effects.

3) Additional pain medications prescribed in case of inadequate pain control, postoperatively.

Methods:

The study will consist of 2 treatment arms and participants are randomized to one of the two arms of the study. It will be double-blinded with two identical capsules formulated by the pharmacy (Mariners Advanced Pharmacy Corp, San Mateo CA) as follows:

Treatment Arm 1: Hydrocodone (5 mg) + Acetaminophen (325 mg) tablet, Q4H PRN pain

Treatment Arm 2: Ibuprofen (200 mg) + Acetaminophen (325 mg) tablet, Q4H PRN pain

In the event of inadequate pain control:

Patients will be requested to take an extra tablet with each dose (Q4H)

OR

We will prescribe Ultram 50 mg Q6H, additionally.

5 pain scorecards will be provided to all patients, each consisting of 4 visual analog scales of 0-10 points (0 - no pain and 10 - most severe pain) to document the intensity of pain experienced at each dosage, along with logging the amount of medication taken (1-2 tabs) and the time it was taken. They will also document any complications/side effects that they experience.

Each participant's baseline pain score based on the pain VAS is documented, and the drugs from their randomized treatment arm dispensed at each participant's preoperative visit.

Enrollment:

Treatment arm 1: Acetaminophen + Hydrocodone

Participants required – 51

Treatment arm 2: Acetaminophen + Ibuprofen

Participants required – 51

Total number of participants required: 102

(Based on power calculations for a non-inferiority clinical trial, to compare Tylenol + Hydrocodone to Tylenol + ibuprofen for controlling postoperative pain where the outcome is the reduction in pain VAS scale. Pain reduction is expected to be 1 for the hydrocodone group or 1 or larger in the ibuprofen group. Assuming a 0.5-point difference is not clinically relevant and standard deviation (SD) of 1)