STUDY PROTOCOL

Title
Effect of topical furosemide on Rhinosinusal polyposis Relapse: A Triple Blinded Randomized Controlled Trial
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General information
IRCT registration number: IRCT201403143186N5
Date registered: May 28, 2014
Expected recruitment start date: 2014-03-21
Expected recruitment end date: 2015-08-22
Funding source: Hamadan University of Medical Sciences
Trial center name: Besat Hospital, ENT clinic
Country: Iran, Islamic Republic Of

Objective
Effect of topical furosemide on rhinosinusal polyposis relapse.

Study design
A triple-blind placebo-controlled randomized trial

Plan
The eligible patients referring to Besat hospital clinic with chronic rhinosinusitis and sinonasal polyposis (according to AAO-HNS) will be enrolled.

Inclusion criteria
Patients with chronic rhinosinusitis and sinonasal polyposis (according to AAO-HNS) who have not responded to medical therapy aged 18 to 60 years old and candidate for FESS.

Exclusion criteria
Pregnancy; history of hypertension and cardiac diseases; hypokalemia; history of tinnitus; history of sensory neural hearing loss and hypersensitivity to Furosemide.

Sample size
82

Gender
Both male and female

Condition
Nasal polyp, ICD code J33

Intervention group
Furosemide spray, twice a day, 2 puffs in each nostril for 2 months.

Control group
Placebo spray, twice a day, 2 puff in each nostril for 2 months.

Primary outcome
Nasal and paranasal sinus polyposis, before intervention, 1 month, 3 months, 6 months after intervention, using SNOT-22 questionnaire, PNS CT scan scoring, VAS, Meltzer grading

**Secondary outcome 1**

Burning sensation 1 month, 3 months, 6 months after intervention using questionnaire

**Secondary outcome 2**

Epistaxis 1 month, 3 months, 6 months after intervention, using questionnaire and physical examination

**Secondary outcome 3**

Hypersensitivity 1 month, 3 months, 6 months after intervention, using questionnaire and physical examination

**Statistical Reporting**

The independent t-test was used for analysis of continuous variables and the Fisher exact test for nominal variables. All statistical analyses were performed at a significance level of 0.05 using Stata software, version 11.

**Approval**

Ethics Committee of Hamadan University of Medical Sciences

Date approved: 2014-02-24

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