

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of intravenous vitamin c on post operative pain in uvulopalatopharyngoplasty (uppp) with tonsillectomy.

Protocol summary

Summary

In the present study we want to investigate the analgesic effects of vitamin C in the patients who undergo UPPP and tonsillectomy. Objectives: 1- To determine and compare the mean pain scores during the first 24 hours after the surgery in both groups. 2- To determine and compare the mean of the systolic, diastolic and arterial blood pressure and the mean heart rate during and after the surgery in both groups. 3- To determine and compare the time interval between the completion of the surgery and the first request for analgesic in both groups . Design: A Phase I or II, Single-Center, Randomized, Double-Blinded, Placebo-Controlled, clinical trial. Setting and conduction: Frothy patients who undergo uvulo-palato-pharyngoplasty and tonsillectomy are randomly divided into two groups by anesthesiologist. The patients are not aware of their groups. For all patients anesthesia induction and maintenance are similar. During the surgery, group C receives vitamin C and group P receives normal saline by anesthesiologist. An anesthesia resident, unaware of the patient's group, fills out the questionnaires. Finally we will analyze the data with a statistical software. Participants: Patients with age of 25-50 years old, ASA (American Society of Anesthesia) physical status I or II ,who are going to have a UPPP and tonsillectomy, are included .Patients with mental retardation, epilepsy, BMI>35 kg/m2, history of chronic pain, liver or renal disease, drug allergy and drug abuse are excluded from the study. Intervention: During the first 30 minutes after the beginning of the surgery, group C receives infusion of 3 gr vitamin C in 500 ml Ringer and group P receives 5 ml normal saline in 500 ml Ringer. Main outcome measures: 1- Post operative pain 2- Heart rate 3- Systolic, diastolic and mean arterial blood pressure 4- Time of the first analgesic request

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404055764N3**

Registration date: **2015-02-15, 1393/11/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

Name

Vida Ayatollahi

Name of organization / entity

Shahid Sadughi University

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadughi medical science university

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2014-03-04, 1392/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous vitamin c on post operative pain in

uvulopalatopharyngoplasty (uppp) with tonsillectomy.

Public title

Effect of intravenous vitamin c on post operative pain.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 25-50 years; both male and female; BMI<35; American Society of Anesthesia (ASA) physical status I or II; underwent uvulopharyngopalatoplasty with tonsillectomy. Exclusion criteria: mental retardation; epilepsy; chronic pain; liver or renal disease; drug abuse and drug allergy.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the Medical Mniversity Shahid Sadoughi

Street address

Shahid Sadoughi Medical sciences university, Bahonar Square

City

Yazd

Postal code

8916978477

Approval date

2012-06-30, 1391/04/10

Ethics committee reference number

28200

Health conditions studied**1****Description of health condition studied**

The effect of vitamin c on uvulopharyngopalatoplasty and tonsillectomy pain

ICD-10 code

Y48.2

ICD-10 code description

Other and unspecified general anaesthetics

Primary outcomes**1****Description**

Post operative pain

Timepoint

Recovery room, 6, 12 and 24 hours post operation

Method of measurement

VAS score

Secondary outcomes**1****Description**

Systolic, Diastolic and Mean blood pressure

Timepoint

Before and during anesthesia, 0,15, 30 and 60 minute after extubation

Method of measurement

mm Hg by Automatic non invasive blood pressure

2**Description**

Heart rate

Timepoint

Before and during anesthesia, 0,15, 30 and 60 minute after extubation

Method of measurement

Before and during anesthesia, 0,15, 30 and 60 minute after extubation

3**Description**

Time of the first analgesic request

Timepoint

Hours postoperation

Method of measurement

Recovery room and ward

Intervention groups**1****Description**

During the first 30 minute after the beginning of the surgery, patients received infusion of 5ml normal saline in 500 ml ringer

Category

Prevention

2

Description

During the first 30 minute after the beginning of the surgery, patients received infusion of 3 gr vitamin c in 500 ml ringer.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

DR Ayatollahi Vida

Street address

No 12, Shahid Sadoughi Hospital, Ebnesina Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of shahid sadoughi medical sciences

Full name of responsible person

DR Mozaffari Hasan

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Shahid Sadoughi medical sciences university, Bahonar square

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, University of shahid sadoughi medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi Medical sciences university

Full name of responsible person

Dr Ayatollahi Vida

Position

Associate Professor, Anesthesiologist

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty