

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Role of thiamine in the management of post-operative analgesia in maxillofacial surgery.

Protocol summary

Summary

(1) Objectives: Thiamine is a water-soluble vitamin of the B complex. First named aneurin for the negative neurological effects if not present in the diet, it was finally assigned the generic name vitamin B1. Thiamine plays a key role in certain metabolic reaction, including: nervous system and muscle functioning; flow of electrolytes in and out of nerve and muscle cells (through ion channels); multiple enzyme processes (via the coenzyme thiamin pyrophosphate); carbohydrate metabolism; and production of hydrochloric acid (which is necessary for proper digestion). Thiamine is generally considered safe and relatively nontoxic, even at high doses. Thiamine also helps convert carbohydrate to fat for storage of potential energy. Thiamine is a major factor in the metabolism of carbohydrate, fat, amino acid, glucose, and alcohol . It is a co-factor of pyruvate dehydrogenase and necessary for aerobic metabolism , that may increase oxygen extraction in critically ill patients. The purpose of this study was to evaluate the ability of intravenous thiamine for postoperative pain reduction in oral and maxillofacial surgery. (2) Design: This is a double-blind randomised clinical trial study, that evaluate the effect of intravenous thiamine on postoperative pain reduction in patients requiring maxillofacial surgery whom will be admitted in the Shiraz-chamran hospital. The following parameters such as: Individual patient information, medical history, the patient's hemodynamic values before- during and after surgery, duration of operation will be recorded. Severity of pain was evaluated by visual analogue scale (VAS) (100-mm) and the amount of opioid consumption after surgery, was recorded in maxillofacial ward. pain was measured after patient transferred to recovery room. (3) Setting and conduct: A total of 50 adult patients were selected for this randomized controlled trial. All subjects were divided into two groups to receive thiamine or placebo. While anesthesiologist, and student project manager would be unaware of an intravenous drugs. (

Medications taken by nurses are randomly coded). An informed consent approved by the Ethics Committee of the Shiraz University of Medical Sciences. The anesthesiologist administered 200 mg of thiamine intravenously with 20 cc of 5% dextrose solution in study group and in the control group patients received placebo (IV) with 20 cc of 5% dextrose solution. Blood pressure and heart rate will be monitored and anesthetic drugs requirements during surgery, postoperative pain and necessity for postoperative opioids immediately after surgery, in the recovery room and until 12 hours after operation will be calculated and recorded. (4) Participants including major eligibility criteria: Inclusion criteria included 16-40year old patients whom were scheduled to undergo maxillofacial surgery! Subjects who had systemic disease and history of drug consumption, history of drug allergic reaction, hepatic and renal dysfunction and lack of signed informed consent will be excluded from the study sample . (5) Intervention: Patients in the study group will be received an intravenous "Thiamine hydrochloride" 200 mg dissolved in Dextrose Water 5% via pump infusion bolus for 15 min and the placebo group will receive " Dextrose Water 5% " as same bolus volume in a 15-minute intravenous infusion. (6) main outcome measures: During surgery heart rate, blood pressure and blood oxygen saturation is recorded at specified intervals and at the end of the operation analgesics usage were recorded. After surgery the patients were monitored for up to 4 hours in the recovery room and pain intensity (VAS 100-mm) is measured by a person who was uninformed about case and control groups every half hour. Pain relief drug consumption for patients will be recorded up to 12 hours in maxillofacial ward. post-operative complications will be asked in the questionnaire. Patient's satisfaction was evaluated as poor (0), moderate (1), good (2), and excellent (3).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403061674N11**

Registration date: **2014-07-03, 1393/04/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-03, 1393/04/12

Registrant information

Name

Hamid Reza Eftekharian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 4001

Email address

eftekhahr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of thiamine in the management of post-operative analgesia in maxillofacial surgery.

Public title

Thiamine (Intravenous Vitamin B1) induced post-operative analgesia in maxillofacial surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included: The patients with systemic disease and no history of drug use, and willingness to cooperate in this study are enrolled! Exclusion criteria included known allergy to the study drug, hepatic and renal dysfunction and lack of signed informed consent will be excluded.

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

City

Shiraz

Postal code

71345-1978

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CT-P-93-7277

Health conditions studied

1

Description of health condition studied

Maxillofacial surgery

ICD-10 code

00

ICD-10 code description

00

Primary outcomes

1

Description

Intensity of postoperative pain

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

VAS

2

Description

Use of narcotic after surgery

Timepoint

To 12 hours after surgery

Method of measurement

Nursing reports

Secondary outcomes

1

Description

post-operative complications of Thiamine

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

Nursing reports

2

Description

Patient's level of satisfaction

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

poor (0), moderate (1), good (2), and excellent (3)

Intervention groups

1

Description

Patients in the interventional group (first group) will be received an intravenous "Thiamine hydrochloride" 200 mg dissolved in Dextrose Water 5% via pump infusion bolus for 15 min.

Category

Treatment - Drugs

2

Description

Patients in the the second group will receive " placebo" as same bolus volume of " Dextrose Water 5% " in a 15-minute intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

Street address

Shiraz University Of Medical Sciences, Shiraz Chamran Hospital, Chamran Blvd., Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Full name of responsible person

Sayed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology, Shiraz University Of 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

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

Position

Assistant Professor

Other areas of specialty/work

Street address

Shiraz University Of Medical Sciences, Shiraz Chamran Hospital, Chamran Blvd., Shiraz

City

Shiraz

Postal code

7194815644

Phone

+98 71 1624 0105

Fax

+98 71 1623 4507

Email

eftekhahr@sums.ac.ir

Web page address

www.sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shiraz University Of Medical Sciences, Shiraz
Chamran Hospital, Chamran Blvd., Shiraz

City

Shiraz

Postal code

7194815644

Phone

+98 71 1624 0105

Fax

+98 71 1623 4507

Email

eftekharr@sums.ac.ir

Web page address

www.sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shiraz University Of Medical Sciences, Shiraz
Chamran Hospital, Chamran Blvd., Shiraz

City

Shiraz

Postal code

7194815644

Phone

+98 71 1624 0105

Fax

+98 71 1623 4507

Email

eftekharr@sums.ac.ir

Web page address

www.sums.ac.ir

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