Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 intraveneous 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 analoug scale (VAS) (100-mm) and the amount of opioid consumption after surgery, was recorded in maxillofacial ward. pain was measured after patient transfered 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
eftekharhr@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
eftekharhr@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
eftekharhr@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
eftekharhr@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