

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

comparision of effect of intervenous administration of dexametason with fentanil on reduction of propofol induced pain during intravenous injection

Protocol summary

Summary

The pain is one of the unpleasant features of the propofol intravenous injection. this study compared the effects of anesthesia with dexamethasone and fentanyl on the reduction of severity and incidence of pain during injection of propofol in surgeries. The study was done as a randomized clinical trial: Patients of 16 to 60 years admitted for general surgery. The patients who received sedative drugs 48hr before operation, have drug allergy, with neurological disorders or mental, drug Addicts, Pregnant women and who require a rapid induction of anesthesia will exclude. From 150 patients who underwent surgery, randomly 50 subjects were placed in normal salin group, 50 in the dexamethasone group and 50 in fentanyl group. Injection of anesthetic drugs was done with Fentanyl at the dose of 100 µgr and dexamethasone at the dose of 8mg and in the normal salin at dose of 5 cc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021015281N2**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Seyedebrahim Sadeghi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 4333 3278

Email address

esadeghi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparision of effect of intervenous administration of dexametason with fentanil on reduction of propofol induced pain during intravenous injection

Public title

effect of intervenous administration of dexametason and fentanil on reduction of propofol induced pain during intravenous injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients of 16 to 60 y/o admitted for general surgery Exclusion criteria: the patients who received sedative drugs 48hr before operation; have drug allergy; with neurological disorders or mental,drug Addicts; Pregnant women and who require a rapid

induction of anesthesia

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Shiraz University of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences Front of Felestin Avenue, ,Zand Ztreet, Shiraz

City
shiraz

Postal code

Approval date
2015-01-26, 1393/11/06

Ethics committee reference number
CT-2015-249

Health conditions studied

1

Description of health condition studied
Complications of anaesthesia

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Effect of fentanil on reduction of propofol induced pain during intravenous injection

Timepoint
1 minute after injection of propofol

Method of measurement
Fill questionnaire and visual scale

2

Description
Effect of dexametason on reduction of propofol induced pain during intravenous injection

Timepoint
1 minute after injection of propofol

Method of measurement
Fill questionnaire and visual scale

Secondary outcomes

1

Description
Dermal side effects

Timepoint
From injection time untill ending of recovery time

Method of measurement
Fill questionnaire

Intervention groups

1

Description
Control group: first group, 5 cc normal salin 0.9 , 1 min before propofol injection

Category
Treatment - Drugs

2

Description
Interventional group: second group, 8 mg dexametason, 5 cc , 1 min before propofol injection

Category
Treatment - Drugs

3

Description
Interventional group: thirth group, 100 micro gram fantanil, 5 cc , 1 min before propofol injection

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
marvdasht hospital
Full name of responsible person
seyed ebrahim sadeghi
Street address
City
marvdasht

Email
esadeghi@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
International Branch, Shiraz University of Medical Sciences
Full name of responsible person
DR kazem samadi
Street address
International Branch of Shiraz University of Medical Sciences, Office, No. 71, Next Alley 1 .Jahad Sazandegi Avenue, Azadi Square, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

International Branch, 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 University of Medical Sciences
Full name of responsible person
DR Seyedebrahim Sadeghi
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Person responsible for updating data

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Assistant Professor
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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