

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparing effect between topical ARNICA pomade and Bupivacaine injection in pain relief at surgical incision for patient with Varicocele operation

Protocol summary

Summary

Aim: Comparison effect between topical ARNICA pomade and Bupivacaine injection in pain relief at surgical incision for patient with Varicocele operation in Hamadan Shahid Beheshti Hospital. Design: double blind randomized clinical trial. Setting: Patients with Varicocele surgery them refer to Shahid Beheshti Hospital in Hamadan in 2017-2018. Inclusion criteria: (a)patients with class 1 or 2 according to the American Society of Anesthesiology scoring criteria; (b)age of 20-60 years;(c)no history of Psychotropic or Opium drugs consumption; (d)Lack of long-term use of nonsteroidal anti inflammatory drugs; (e)Lack of systemic disease; (f)Lack of sensitivity to medications used. Exclusion criteria: (a)Lack of any of the inclusion criteria; (b)Lack of patient cooperation. Patients were randomly placed into three groups every group have 42 member and using general anesthesia and same Protocols and primary outcome is pain severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702149597N2**
Registration date: **2017-03-13, 1395/12/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

Name

Seyed Mohamad Zolhavarieh

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect between topical ARNICA pomade and Bupivacaine injection in pain relief at surgical incision for patient with Varicocele operation

Public title

Comparing effect between topical ARNICA pomade and Bupivacaine injection in pain relief at surgical incision for patient with Varicocele operation in Hamedan Shahid Beheshti Hospital on 2017-2018

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a)patients with class 1 or 2 according to the American Society of Anesthesiology scoring

criteria; (b)age of 20-60 years;(c)no history of Psychotropic or Opium drugs consumption; (d)Lack of long-term use of nonsteroidal anti inflammatory drugs; (e)Lack of systemic disease; (f)Lack of sensitivity to medications used. Exclusion criteria: (a)Lack of any of the inclusion criteria; (b)Lack of patient cooperation.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hamadan University of Medical Sciences

Street address

ice-chancellor of Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-01-28, 1395/11/09

Ethics committee reference number

IR.UMSHA.REC.1395.502

Health conditions studied

1

Description of health condition studied

Pain localized to other parts of lower abdomen

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description

Pain severity

Timepoint

1, 6, 12, , and 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

side effects of of drugs

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

questionnaire

2

Description

Opium dose (mg) usage

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

questionnaire

3

Description

Hemodynamic status

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

Physical examination

Intervention groups

1

Description

1hours before surgery, 5g of topical Arnica pomade use.

Category

Treatment - Other

2

Description

Injection (10 ml) bupivacaine 0.25% at the end of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Seyed Mohammad Zolhavarieh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Vice-chancellor of Research and Technology,
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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 of Research and Technology, Hamadan
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
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Person responsible for updating data

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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