

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation the effect of preoperative education on postoperative pain in patient undergoing Percutaneous Nephrolithotomy (PCNL)

Protocol summary

Summary

The aim of this study is evaluation of the effect of preoperative education on postoperative pain and anxiety in patients undergoing Percutaneous NephroLithotomy (PCNL). This study is single blinded randomized clinical trial, included 130 patients which randomly divide into 65 patients in case and control group (outcome assessors blinded). The inclusion criteria are age more than 15 year old, being mentally oriented to the situation, no addiction to narcotics or strong analgesics, no previous psychological disease, no severe pain due to underlying disease, no emergency condition and sign the consent form. The exclusion criteria are the patients who are not able to fulfill the questionnaire, simultaneous intervention and unusual complications such as perforation of the bowels which aggravates the pain. The case group will get extra information about the surgery and renal stones, by using pamphlets and face to face education while the control group didn't get this extra information and only basic information will deliver to them. Primary outcome measure will be postoperative pain and anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011427135N3**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Saeide Bahrani

Name of organization / entity

Isfahn University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of preoperative education on postoperative pain in patient undergoing Percutaneous Nephrolithotomy (PCNL)

Public title

Evaluation the effect of preoperative education on postoperative pain and anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria are: age more than 15 year old; being mentally oriented to the situation; no addiction to narcotics or strong analgesics; no previous psychological disease; no severe pain due to underlying disease; no

emergency condition and sign the consent form. The exclusion criteria are: the patients who are not able to fulfill the questionnaire; simultaneous intervention and unusual complications such as perforation of the bowels which aggravates the pain.

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib st, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2013-05-14, 1392/02/24

Ethics committee reference number

191093

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Anxiety

Timepoint

Once after surgery

Method of measurement

Beck Anxiety Inventory

2

Description

Pain

Timepoint

After surgery, every 3 hours until discharge

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group received specific information both verbally and in a leaflet. The information content was about, what happens before surgery, who they would meet during the day (nurses, anesthetist, and so on) and some basic scientific information included introduction to urinary ducts, etiology of kidney stones and their types, Kidney stones sign and symptoms, diagnostic methods, preventive methods, brief explanation about PCNL and frequently asked questions of that.

Category

Other

2

Description

control group: control group did not receive the mentioned information.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Street address

Alzahra hospital, Sofeh st, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Miss Pahlavan

Street address

Isfahan University of Medical Sciences, Hezar Jarib st, Isfahan

City

Isfahan

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, Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Sayed Ali Emami

Position

General Practitioner

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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