Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Acupressure on Pain Severity, Anxiety, and Vital Sign in Patients with Renal Colic Referring to the Emergency Department

Protocol summary

Study aim
Determination of the Effect of Acupressure on Pain Intensity, Anxiety, and Vital Signs in Patients with Renal Colic Presenting to the Emergency Department

Design
A randomized, parallel-group, controlled clinical trial, open-label, phase 3, including 100 patients. Randomization was performed using a number table.

Settings and conduct
The study will be conducted in the Emergency Department of LabafiNejad Hospital. Eligible patients, after providing informed consent, will be assigned to the intervention or control group. Interventions will be applied according to the defined protocol, and data on pain intensity, anxiety, and vital signs will be collected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed renal colic diagnosis, age 18–65 years, full consciousness (GCS=15), mild to moderate pain (VAS 3–6). Exclusion criteria: Voluntary withdrawal, history of abdominal or genitourinary surgery, need for hospitalization or treatments outside the study protocol, lack of continuous cooperation with study procedures.

Intervention groups
Intervention group: The intervention group will receive combined acupressure on the Qiu point along the bladder meridian and routine pharmacological treatment. Acupressure will be performed by a trained researcher in three 1-minute sessions with 30-second rests. The procedure will be stopped if the patient experiences discomfort. Control group: The control group will receive routine emergency care, including pharmacological pain relief, without any additional interventions.

Main outcome variables
Pain intensity; Anxiety level; Vital signs including pulse rate, blood pressure and respiratory rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250802066727N1**
Registration date: **2025-11-05, 1404/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-05, 1404/08/14**
Update count: **0**

Registration date
2025-11-05, 1404/08/14

Registrant information
Name
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Name of organization / entity
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2025-10-20, 1404/07/28
Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Effect of Acupressure on Pain Severity, Anxiety, and Vital Sign in Patients with Renal Colic Referring to the Emergency Department

Public title

The Effect of Acupressure on Pain Severity, Anxiety, and Vital Sign in Patients with Renal Colic Referring to the Emergency Department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of renal colic by the emergency department physician Age between 18 and 65 years Full consciousness (Glasgow Coma Scale score = 15) Pain intensity at the time of enrollment ranging from mild to moderate, with a score of 3 to 6 on the Visual Analogue Scale (VAS)

Exclusion criteria:

Voluntary withdrawal from participation at any stage of the study History of abdominal or genitourinary surgery Need for emergency hospitalization or receiving specialized treatments outside the study protocol Lack of consistent cooperation with the study instructions and requirements

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After confirming the inclusion criteria, eligible participants will be randomly assigned into two groups using simple randomization. For this purpose, each participant will be assigned a number generated by a random number table or statistical software such as SPSS. The participants' names will be recorded in the order of their entry into the study, and the corresponding numbers will be extracted from the table. Even numbers will be assigned to the intervention group (combined acupressure and pharmacological method), and odd numbers will be assigned to the control group (routine pharmacological method). To ensure allocation concealment, the group assignments of each participant will be placed in sealed, opaque envelopes prepared and numbered by an individual who is not a member of the research team. The allocation ratio in this study will be 1:1.

Blinding (investigator's opinion)

Not 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 the Faculties of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of

Street address

Faculty of Nursing and Midwifery, Valiasr St., at the intersection with Ayatollah Hashemi Rafsanjani Highway, in front of Shahid Rajaei Heart Hospital, Tehran, Iran.

City

Tehran

Province

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Postal code

1996835119

Approval date

2025-10-20, 1404/07/28

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1404.163

Health conditions studied

1

Description of health condition studied

Acute renal colic pain in patients referred to the emergency department

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain intensity measured by the Visual Analogue Scale (VAS)

Timepoint

before the intervention, 15 minutes, and 30 minutes after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Anxiety level measured by the Spielberger State-Trait

Anxiety Inventory (STAI-S)

Timepoint

before the intervention, 15 minutes, and 30 minutes after the intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

2

Description

Vital signs including pulse rate, respiratory rate, blood pressure

Timepoint

before the intervention, 15 minutes, and 30 minutes after the intervention

Method of measurement

Blood pressure will be measured using a digital sphygmomanometer, radial pulse rate will be counted manually, and respiratory rate will be recorded by observing chest movements.

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive a combined intervention of acupressure and pharmacological treatment. Acupressure will be performed by a trained and qualified researcher on the Qiu point (corresponding to BL-23 in Traditional Chinese Medicine) along the bladder meridian in the lumbar region. The patient will lie on the side with the painful area on top. Acupressure will be applied using the thumb or index finger gradually, uniformly, and continuously, with a tolerable pressure. The procedure consists of three 1-minute pressure sessions with 30-second rests in between, totaling approximately 5 minutes. The researcher will monitor patient tolerance continuously, and the procedure will be stopped immediately if the patient feels discomfort or wishes to discontinue. Simultaneously, participants will receive the routine pharmacological pain relief according to the emergency department protocol

Category

Treatment - Other

2

Description

Control group: Participants in the control group will receive routine emergency care including pharmacological pain relief according to the emergency department protocol, without any additional interventions such as acupressure or other non-pharmacological methods.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Hospital

Full name of responsible person

Fatemeh Hasan Doost

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Arabi St., Daneshjoo Blvd., Velenjak, Tehran, Iran.

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fatemeh Hasan Doost

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Faculty of Nursing and Midwifery, Valiasr St., at the intersection with Ayatollah Hashemi Rafsanjani Highway, in front of Shahid Rajaei Heart Hospital, Tehran, Iran.

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Person responsible for scientific inquiries

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data will be shared in a coded form, ensuring the confidentiality of participants' names and personal information.

When the data will become available and for how long
Start of access period after results publication

To whom data/document is available
Researchers affiliated with academic and scientific institutions

Under which criteria data/document could be used
For further investigations, addressing study limitations, and use in clinical practice

From where data/document is obtainable
Dr. Fatemeh Hasan Doost fateme_hd_66@yahoo.com

What processes are involved for a request to access data/document

After sending an email to the author, the required data will be provided while respecting intellectual property rights.

Comments