Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of hydrotherapy in the treatment of patients with lumbar disc herniation

Protocol summary

Study aim
Evaluation of the effect of hydrotherapy in patients with lumbar disc herniation

Design
A Single-Blinded, Randomized clinical trial, with parallel groups on 96 patients followed for 3 to 6 months

Settings and conduct
96 patients suffering from Lumbar disc herniation referred to orthopedic clinic of Imam Khomeini Hospital will be Randomized to one of two groups of Analgesic Treatment and Hydrotherapy with analgesic treatment. Patients could not be blinded but the data collectors and outcome assessors are blinded to assignment.

Participants/Inclusion and exclusion criteria
Lumbar Disc Herniation Patients with informed consent who meet the inclusion criteria will enter the study. Inclusion Criteria: Absence of Cardiovascular Disease, Absence of Gastrointestinal Disease, Absence of any mental disorder related to water Exclusion Criteria: Adverse reaction to study drugs

Intervention groups
Intervention group: 2 hour Hydrotherapy sessions twice weekly, for 3 to 6 months with Analgesic Treatment with Celecoxib or Naproxen Twice a day Control group: Analgesic Treatment with Celecoxib or Naproxen Twice a day for 3-6 months

Main outcome variables
The amount of change in Lower back and lower limb pain after 3 to 6 months based on Visual Analogue Scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200819048460N1**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **retrospective**
Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date
2020-11-04, 1399/08/14

Registrant information

Name
Akram Vahabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3780 2973

Email address
paradise682002@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-23, 1397/02/03

Expected recruitment end date
2020-02-29, 1398/12/10

Actual recruitment start date
2018-06-10, 1397/03/20

Actual recruitment end date
2020-04-13, 1399/01/25

Trial completion date
2020-04-13, 1399/01/25

Scientific title
The effect of hydrotherapy in the treatment of patients with lumbar disc herniation

Public title
Evaluation of the effect of hydrotherapy in lumbar disc herniation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lumbar disc herniation confirmed by an orthopedic specialist Consent to enter the study Absence of Cardiac disease (due to the possibility of complications of celecoxib consumption in coronary artery disease patients) Absence of gastrointestinal disease(like peptic ulcer disease) Absence of Mental Disorders related to water (like phobias)

Exclusion criteria:

Hypersensitivity to naproxen or celecoxib that patients can not use any of these two drugs.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study computerized block randomization (block sizes of 4 and 6) will be carried out. An independent clinical epidemiologist, who will not be involved in the conduct of the study, uses a computerized block randomization program (STATA14 software) to produce the allocation codes. The randomization sequences will be concealed in lightproof, sealed envelopes. The research assistant opens sealed, numbered, opaque envelopes containing allocation codes. The eligible participants will be randomly divided into two equal groups (Hydrotherapy or control) according to the randomization list after signing informed consent form.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the allocation of a group to hydrotherapy, it is not possible to blind patients. But the second investigator of the research project who is blinded to the assignment of patients, will complete the questionnaire at the end of the treatment. Also the data will be analyzed without any information about group selection

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.AJUMS.REC.1398.481

Health conditions studied

1

Description of health condition studied

Disc bulging

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

Back and lower limb pain score in patients with lumbar disc herniation based on Visual Analogue Scale

Timepoint

At the beginning of the intervention and 3 to 6 months after hydrotherapy and medication.

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

1

Description

Daily quality of life score based on Oswestry low back pain disability questionnaire

Timepoint

En At the beginning of the intervention and 3 to 6 months after hydrotherapy and medication.

Method of measurement

The Oswestry low back pain disability questionnaire

Intervention groups

1

Description
Intervention group: Patients assigned to this group undergo Hydrotherapy sessions, which include walking in a pool filled with water with a depth of 1.5 meters, twice a week, with each session lasting for two hours, for a duration of three to six months. Treatment with 500 mg Celecoxib capsules (Dr Aabidi Pharmaceutical Company) is used twice a day. Naproxen capsules (500 mg, Twice a day Tolid Daru Pharmaceutical Company, Tehran) is used instead of Celecoxib if the patients suffer from coronary artery disease.

Category
Treatment - Other

2

Description
Control group: Patients in this group will undergo daily treatment with 500 mg Celecoxib capsules (Dr Aabidi Pharmaceutical Company) used twice a day. Naproxen capsules (500 mg, Twice Daily Tolid Daro Pharmaceutical Company, Tehran) is used instead of Celecoxib if the patients suffer from coronary artery disease.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Imam Khomeini Hospital

Full name of responsible person
Payam Mohammad Hosseini

Street address
Imam Khomeini Hospital, 24 meters Avenue, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3222 3818

Email
Payam_m_h@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahdi Ahmadi Moghadam

Street address
Ahwaz Jundishapur University of Medical Sciences, Golestan BLVD, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135815751

Phone
+98 61 3336 2414

Fax
+98 61 3336 1544

Email
iitc@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Payam Mohammad Hosseini

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Imam Khomeini hospital, 24m street

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3222 3818

Email
Payam_m_h@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person
Payam Mohammad Hoseeini

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Imam Khomeini Hospital, 24m street

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3222 3818

Email
Payam_m_h@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Payam Mohammad Hosseini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Imam Khomeini Hospital,24M Street

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3222 3818

Email
Payam_m_h@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available