

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the Effect of an Iranian Massage (Fateh Method) on Pain and Disability of Patients Suffering from Chronic Low Back Pain with Physiotherapy and Acupuncture

Protocol summary

Study aim

Comparing the effect of massage, physiotherapy and acupuncture on pain and disability due to chronic low back pain

Design

Clinical Trial with two intervention and one control groups, parallel groups, non-randomized, not blind, with 90 patients, enrolled between Shahrivar and Mehr 98, and followed for one month

Settings and conduct

In this study, designed as a controlled clinical trial, patients suffering from chronic low back pain more than 3 months are studied who come to Tehran University of Medical Sciences clinics in Imam Khomeyni hospital, Tooba building, Valiasr and Khark building. Patients are selected according to inclusion criteria and examined by a doctor. After elimination of patients with exclusion criteria, the research is explained to patients and the ones who accept to be part of the study, fill the written consent form out. Patients are investigated in these three groups: massage, acupuncture and physiotherapy. Lifestyle and exercise are taught to the patients to relieve pain and exercise instructions are given to each. Diclofenac is also given to patients to use if needed (one 100 mg Tablet of Iran Najou pharmacy company) and write down the exact number of tablets carefully. Pain level and disability due to low back pain is evaluated three times in each group: before beginning therapy, after completing therapy and one month after finishing therapy. This is done by using VAS and Roland-Morris Questionnaires.

Participants/Inclusion and exclusion criteria

chronic low back pain without paresthesia and radicular pain and any specific pathology, pain more than 3 months, confirmation of low back pain and clinical examination by expert to exclude pathologies

Intervention groups

Intervention group 1: Patients undergoing massage therapy
Intervention group 2: Patients undergoing acupuncture
Control group: Patients undergoing physiotherapy

Main outcome variables

Pain and disability due to chronic low back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042118N1**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-21, 1398/06/30**

Update count: **0**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

Parva Namiranian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 3198

Email address

p-namiranian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-19, 1398/06/28

Expected recruitment end date

2019-12-19, 1398/09/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effect of an Iranian Massage (Fateh Method) on Pain and Disability of Patients Suffering from Chronic Low Back Pain with Physiotherapy and Acupuncture

Public title
Effect of Fateh Massage on Low Back Pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic low back pain without paresthesia and radicular pain and any specific pathology Pain more than 3 months Confirmation of low back pain and clinical examination by expert to exclude pathologies

Exclusion criteria:
Pregnancy or breastfeeding History of surgery due to low back pain Red flags that need more investigations or surgery Ankylosing Spondylitis Neuropathy or neurologic problems in physical examination Severe untreated Scoliosis Infection in low back or spinal cord Acute radiculopathy Mental problems Acute trauma Rheumatoid inflammatory disorders Uncontrolled Hypertension or Diabetes Mellitus Digestive system problems including stomach pain or ulcer, IBD Low back pain due to Uterus conditions Signs of weakness or Emtela Use of Digoxin, Warfarin; Heparin Addiction to alcohol or drugs and so on History of epidural or transforaminal injection of anesthetics or corticosteroids during 4 weeks prior to start of treatment

Age
From **19 years** old to **69 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description
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 Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Ghods street crossing Keshavarz Bld

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-12-15, 1397/09/24

Ethics committee reference number

IR.TUMS.VCR.REC.1397.667

Health conditions studied

1

Description of health condition studied

chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Loin pain, Low back strain, Lumbago NOS

Primary outcomes

1

Description

pain level due to low back pain

Timepoint

Before starting study, after the intervention, one month after intervention

Method of measurement

Visual Analogue Scale questionnaire

2

Description

Disability level due to low back pain

Timepoint

Before starting study, after the intervention, one month after intervention

Method of measurement

Roland Morris disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: patients are selected according to inclusion criteria and examined by a doctor. After elimination of patients with exclusion criteria, the research is explained to patients and the ones who accept to be part of the study, fill the written consent form out. In this group 10 sessions of massage with the special method of Fateh -deep fascial release- is done. lifestyle and exercise are taught to the patients to relieve pain and exercise instructions are given to each. Diclofenac is also given to patients to use if needed (one 100 mg Tablet of Iran Najou pharmacy company) and write down the exact number of tablets carefully.

Category

Rehabilitation

2

Description

Intervention group 2: patients are selected according to inclusion criteria and examined by a doctor. After elimination of patients with exclusion criteria, the research is explained to patients and the ones who accept to be part of the study, fill the written consent form out. Acupuncture patients receive 10 sessions of therapy each 20 minutes, twice a week. lifestyle and exercise are taught to the patients to relieve pain and exercise instructions are given to each. Diclofenac is also given to patients to use if needed (one 100 mg Tablet of Iran Najou pharmacy company) and write down the exact number of tablets carefully.

Category

Rehabilitation

3

Description

Control group: patients are selected according to inclusion criteria and examined by a doctor. After elimination of patients with exclusion criteria, the research is explained to patients and the ones who accept to be part of the study, fill the written consent form out. Patients of physiotherapy group receive 10 sessions of standard physiotherapy for chronic low back pain. lifestyle and exercise are taught to the patients to relieve pain and exercise instructions are given to each. Diclofenac is also given to patients to use if needed (one 100 mg Tablet of Iran Najou pharmacy company) and write down the exact number of tablets carefully.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Valiasr traditional medicine building

Full name of responsible person

Ahmad Fateh

Street address

no 79, next to Sahel deadend, Razi street, Valiasr junction, Hazrate Valiasr traditional medicine building

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6676 7355

Email

info@nobaan.com

2

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Seyede Zahra Emami Razavi

Street address

End of Keshavarz bld, Imam Khomeini hospital

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

3

Recruitment center

Name of recruitment center

Tooba health building

Full name of responsible person

Dr. Mohammad Hossein Ayati

Street address

S Felestin St, Tooba health building

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6695 6749

Email

info@toobatim.ir

4

Recruitment center

Name of recruitment center

Khark traditional medicine building

Full name of responsible person

Dr. Mohammad Hossein Ayati
Street address
No 10, Khark street, Enghelab avenue
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6675 4151
Email
info@stpm.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Ali Sahraiyani
Street address
Central building of Tehran University of Medical Sciences, Ghods street, Keshavarz bld
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Parva Namiranian

Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
No 6, Entesariyeh st., 2nd alley, north karegar street
City
Tehran
Province
Tehran
Postal code
1413915518
Phone
+98 21 8800 3198
Fax
Email
p-namiranian@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hossein Ayati
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
North sarparast, Ahmadih health building
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8897 6527
Email
mh-ayati@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Parva Namiranian
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
No 6, Entesariyeh st., 2nd alley, north karegar street

City

Tehran

Province

Tehran

Postal code

1413915518

Phone

+98 21 8800 3198

Fax**Email**

p-namiranian@razi.tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available