

The therapeutic value of acupoint sensitization for patients with adhesive capsulitis (frozen shoulder)

Submission date 29/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/12/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Recent studies have confirmed the phenomenon of acupoint sensitization in patients with frozen shoulder. However, the curative effect of acupuncture on patients with frozen shoulder with different degrees of acupoint sensitization is unclear. Therefore, the aim of this study is to explore the clinical effectiveness of acupoint sensitization points in patients with frozen shoulder.

Who can participate?

Patients aged 18 to 75 years with frozen shoulder with a definite diagnosis and a disease course of more than 6 weeks

What does the study involve?

Patients will be divided into a high-sensitivity group and a low-sensitivity group. Both groups were given basic treatment measures to guide shoulder joint functional exercise. In addition, according to the results of the pressure-pain sensitivities exploration, acupuncture treatment was given to the five points with the highest percentage of pressure pain thresholds reduction in patients in the high-sensitivity group and acupuncture treatment was given to the five points with the lowest percentage of pressure pain thresholds reduction in patients in the low-sensitivity group. The exploration of acupoint pressure-pain sensitivities was determined by a trained doctor of traditional Chinese medicine who was not involved in the study and knew the specific group of patients. After the ranking of acupoint pressure-pain sensitivities is determined, the doctor mentioned above will inform the therapist of the acupuncture points that need to be applied, but not mention the pressure-pain sensitivities degree of the acupuncture points that need to be treated.

What are the possible benefits and risks of participating?

The benefit of this research is that it could relieve patients' pain. Acupuncture therapy rarely causes adverse reactions, and the rare adverse reactions are local skin adverse reactions, including subcutaneous bleeding or local skin allergy.

Where is the study run from?
Luoyang Orthopedic Hospital of Henan Province (China)

When is the study starting and how long is it expected to run for?
March 2023 to February 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Ms Qiuyuan Wang, 1010707935@qq.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Qiuyuan Wang

ORCID ID
<http://orcid.org/0000-0003-0903-2917>

Contact details
NO. 82 Qiming South Road
Luoyang
China
471000
+86 (0)18003797673
1010707935@qq.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Acupuncture for adhesive capsulitis (frozen shoulder) with sensitive acupoints: a randomized controlled trial

Study objectives

The curative effect of acupuncture at acupoints with high sensitivity is better than that at acupoints with low sensitivity in the treatment of frozen shoulder.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 07/11/2023, Ethics Committee of Luoyang Orthopedic Hospital of Henan Province (Orthopedic Hospital of Henan Province, No. 82 Qiming South Road, Luoyang, 471000, China; +86 (0)379 63546181; lyzgll@sina.com), ref: 2023ZXKT0007-01

Study design

Randomized double-blind positive-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Efficacy

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Acupuncture at acupoints with different pressure-pain sensitivities for adhesive capsulitis (frozen shoulder)

Interventions

Randomization: A researcher who is not involved in subsequent studies will use computer-generated random sequences which are put in a sealed envelope for random grouping.

Patients will be divided into a high-sensitivity group and a low-sensitivity group. Both groups were given basic treatment measures to guide shoulder joint functional exercise. In addition, according to the results of the pressure-pain sensitivities exploration, acupuncture treatment was given to the five points with the highest percentage of pressure pain thresholds reduction in patients in the high-sensitivity group and acupuncture treatment was given to the five points with the lowest percentage of pressure pain thresholds reduction in patients in the low-sensitivity group. The exploration of acupoint pressure-pain sensitivities was determined by a trained doctor of traditional Chinese medicine who was not involved in the study and knew the specific group of patients. After the ranking of acupoint pressure-pain sensitivities is determined, the doctor mentioned above will inform the therapist of the acupuncture points that need to be applied, but not mention the pressure-pain sensitivities degree of the acupuncture points that need to be treated.

Acupuncture operation method: A specialized therapist will help the patient select a suitable position, use iodopol for routine disinfection of local skin, and then insert a disposable sterile acupuncture needle (Huatao brand, 0.30 mm × 25 mm) into the acupoint, and lift and twist the needle after the patient feels the acid swelling. Each treatment lasted 30 minutes, once a day. A treatment diary is used to monitor and evaluate the course of treatment.

Intervention Type

Supplement

Primary outcome measure

The following primary outcome measures are assessed at baseline, the end of treatment, 4, and 8 weeks after the end of treatment:

1. Pain is measured using a visual analogue scale (VAS)
2. Shoulder joint function is measured using the motion of the shoulder joint in all directions
3. Shoulder joint function is measured using a Shoulder Pain and Disability Index (SPADI)

Secondary outcome measures

1. Acupoint sensitization is measured using pressure pain thresholds at baseline, the end of treatment, 4, and 8 weeks after the end of treatment
2. Shoulder joint function is measured using rotator cuff quality of life (RC-QoL) at baseline, the end of treatment, 4, and 8 weeks after the end of treatment.
3. The incidence of possible complications related to acupuncture is measured using a record on the participant information sheet after treatment.

Overall study start date

10/03/2023

Completion date

10/02/2024

Eligibility

Key inclusion criteria

Patients with frozen shoulder with definite diagnosis and disease course of more than 6 weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Patients with severe pain at rest (VAS score over 70 mm)
2. The affected shoulder has more than 50% limited motion during two or more exercises compared to the healthy shoulder
3. Patients with other shoulder diseases (such as rotator cuff injury), previous shoulder surgery, or major injury history
4. Patients with cervical spine disease
5. History of anti-inflammatory drug use within 2 weeks before clinical trial, and history of intra-articular steroid injection within 3 months
6. Taking medication for mental illness
7. Have fainted during acupuncture treatment

Date of first enrolment

01/12/2023

Date of final enrolment

05/02/2024

Locations**Countries of recruitment**

China

Study participating centre

Luoyang Orthopedic Hospital of Henan Province

Department of Orthopedic Surgery

No. 82 Qiming South Road

Luoyang City

China

471000

Sponsor information**Organisation**

Luoyang Orthopedic-Traumatological Hospital of Henan Province

Sponsor details

No. 82 Qiming South Road

Luoyang City

China

471000
+86 (0)379 63546550
zggy6354@sina.com

Sponsor type
Hospital/treatment centre

Website
<http://www.lyzhenggu.cn/>

ROR
<https://ror.org/05br7cm44>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Ms Qiuyuan Wang (1010707935@qq.com). Consent will be obtained from participants to share anonymized data. This will be made available subject to a data-sharing agreement. Data will only be shared after there is an appropriate agreement in place and anonymized prior to sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version Case report form and study outcome measure forms		11/12/2023	No	Yes