ISRCTN77430077 https://doi.org/10.1186/ISRCTN77430077

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

Submission date
29/11/2023

Recruitment status
No longer recruiting

Registration date
13/12/2023

Overall study status
Completed

Last Edited
11/12/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
https://orcid.org/0000-0003-0903-2917

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

Additional identifiers

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

Study type(s)
Efficacy

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(s)
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)

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

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

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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