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The effectiveness of electroacupuncture for Parkinson's disease pain

Submission date
07/03/2021

Recruitment status
No longer recruiting

Registration date
24/04/2021

Overall study status
Completed

Last Edited
04/05/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a common chronic progressive neurological disease in middle-aged and elderly people, accompanied by various movement and non-movement symptoms. Skeletal muscle pain is one of the most common PD symptoms, and has often been neglected and has not been properly managed. Electroacupuncture (EA) has received attention as a promising intervention for pain, and some previous studies have reported that this intervention may be beneficial for treating PD patients with skeletal muscle pain. This study aims to explore how practical and effective EA is for PD patients with skeletal muscle pain.

Who can participate?
Adults aged between 30 and 80 years with a diagnosis of Parkinson's disease and chronic musculoskeletal pain.

What does the study involve?
Parkinson’s disease patients will be asked to join this study while they visit Beijing TCM hospital’ s acupuncture department. The trial will be explained to participants and will be asked to sign an informed consent form. Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group will receive 20 sessions of electroacupuncture treatment over 4 weeks. The other group will receive 20 sessions of mock electroacupuncture treatment over 4 weeks using non-penetrating flat needles. The study lasts one month in total. Participants also complete online questionnaires and assessments before receiving treatment and after 2 and 4 weeks. The muscle tension of participants will be measured by ultrasound elastography scan before and after the treatment.

What are the possible benefits and risks of participating?
Relief of pain in PD patients may be a possible benefit while participating in this study. Improvements to the patient's Parkinson skeletal muscle pain are not guaranteed in the controlled group. If the symptoms are not improved due to the control group treatment, normal acupuncture treatment can be provided after the test is completed. The information obtained from this study could possibly benefit patients with the same condition in the future.

The main risk of acupuncture would be temporary pain, a sense of itching or swelling, and other possible side effects such as slight bleeding, bruising, or fainting. Patients with any of these side effects will receive immediate medical care, and the study team will reassess whether they can continue to accept treatment.

Where is the study run from?
Beijing Traditional Chinese Medicine Hospital acupuncture department (China)

When is the study starting and how long is it expected to run for?
February 2021 to February 2022

Who is funding the study?
Beijing Traditional Chinese Medicine Hospital (China)

Who is the main contact?
Dr. Shaosong Wang
wangshaosong@bjzhongyi.com

Contact information

Type(s)
Scientific

Contact name
Ms Ching Yan Lilian Fung

Contact details
Beijing Traditional Chinese Medicine Hospital
No. 23, Art Museum Back Street
Dongcheng District
Beijing
China
100010
+86 (0)17812096297
wangshaosong@bjzhongyi.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

A clinical randomized controlled study of electroacupuncture for Parkinson's skeletal muscle pain

Study objectives
Electroacupuncture can relieve Parkinson's skeletal and muscle pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2021, Beijing Traditional Chinese Medical Hospital Ethics Committee (Beijing Traditional Chinese Medicine Hospital, No. 23, Art Museum Back Street, Dongcheng District, Beijing; +82 010 8970 6734; no email address available), ref: 2020BL02-072-02

Study design
Single-center interventional randomized single-blinded parallel controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Skeletal muscle pain in patients with Parkinson's disease

Interventions
Participants will be randomly allocated (1:1) to either the treatment or the control group. Treatment duration is 1 month with assessments at baseline (before the intervention), 2, and 4 weeks.

Treatment group:
20 sessions of electroacupuncture treatment over 4 weeks. Acupoints are selected according to TCM master He Puren’s experience in treating Parkinson’s disease, including acupoints: Baihui (GV20), Qihai (CV6), Lieque (LU7), Tinggong (SI19), upper limb pain: Jianyu (LI15), Quchi (LI11) + Ashi point; lower limb pain: Futu (ST32), Yanglingquan (SP9) + Ashi point; pierce 10-30 mm with stainless steel needles (1.5 inches of Huatuo brand), and when the patient has the feeling of “Deqi”, apply Huatuo brand SDZ-V EA apparatus (upper limbs: take Jianyu (LI15), Quchi (LI11); lower limbs: take Futu (ST32), Yanglingquan (SP9), choose the density wave, the frequency is 2 Hz Qod /100 Hz Qod, the needle is retained for 30 minutes.

Control group:
20 sessions of mock electroacupuncture treatment over 4 weeks using sham needles (Park needle). The acupoints selection is the same as the treatment group. The flat-head needle is inserted into a Park needle tube, and the needle body is tapped to the needle, which creates a feeling of acupuncture, but the flat-head needle does not puncture the skin. Electrodes are applied but not energized, and the needle is retained for 30 minutes.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Pain measured using King's Parkinson's Disease Pain Scale at baseline, 2, and 4 weeks

Key secondary outcome(s))
1. Pain measured using visual analogue scoring at baseline, 2, and 4 weeks
2. Daily life ability measured using Parkinson's composite score sheet at baseline, 2, and 4 weeks
3. Muscle tension measured using Modified Ashworth score at baseline, 2, and 4 weeks
4. Depression measured using Hamilton Depression Scale at baseline, 2, and 4 weeks
5. Muscle tension measured using real-time shear wave ultrasound elastography at baseline and 4 weeks

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Diagnosis of Parkinson's disease and chronic musculoskeletal pain
2. Agrees to participate in the trial and signs an informed consent form
3. Aged between 30 and 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe heart, liver, kidney, or other organ dysfunction
2. Schizophrenia, malignant tumors, blood system, immune system, or metabolic dysfunction
3. Combined with other types of dementia (such as vascular dementia, frontotemporal dementia, or Alzheimer's disease)
4. Severe cognitive impairment and language impairment
5. Diagnosed with Parkinson's syndrome or Parkinson's superimposed syndrome
6. Poor treatment compliance or unable to cooperate with treatment
7. Do not agree to participate in this research
8. Physical pain caused by other diseases

Date of first enrolment
01/03/2021

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
China

Study participating centre
Beijing Traditional Chinese Medicine Hospital
Beijing Traditional Chinese Medicine Hospital
No. 23, Art Museum Back Street
Dongcheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Traditional Chinese Medicine Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	version V2.0				

Protocol file	08/02/2021	04/05/2021	No	No