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# Evaluation of clinical efficacy and safety of traditional chinese medicine for oral and external use combined with physical therapy in patients undergoing knee arthroplasty

**Submission date**
25/11/2025

**Recruitment status**
No longer recruiting

**Registration date**
18/12/2025

**Overall study status**
Completed

**Last Edited**
16/12/2025

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
This study was designed to evaluate the clinical efficacy and safety of traditional Chinese medicine (TCM) combined with physical therapy in patients undergoing knee arthroplasty.

Who can participate?
Adult patients treated with underwent knee arthroplasty.

What does the study involve?
To ensure the randomness of the grouping, the 106 patients who underwent knee replacement were divided into experimental and control groups using the random number table method, with 53 patients in each group.

Randomization:
Specifically, a professional statistical software was first used to generate a random number table, which contained a series of randomly arranged numbers. Following this, all patients who met the inclusion criteria were numbered according to their order of admission, from 1 to 106. Finally, based on the numbers in the random number table, patients were assigned to the control group or the experimental group; for example, odd numbers in the random number table corresponded to the control group, and even numbers corresponded to the experimental group.

Both groups were informed that they should consume a light diet after the operation and strive to keep the knee warm. When the symptoms were obvious, the knee became stiff. After the symptoms were relieved, the stiffness gradually decreased, but the activity was minimised.

The control group
Conventional drug therapy combined with physical therapy, including analgesic drugs (celecoxib 200 mg twice daily) and anti-inflammatory drugs (diclofenac sodium 75 mg twice daily). These

medications were selected based on the Enhanced Recovery After Surgery (ERAS) Society recommendations for perioperative care in joint replacement surgery.

The experimental group
Oral and external use of TCM combined with physical therapy. The oral drugs included osteoarthritis granules and Duhuo Sanqi Xiaotong granules. The external drug was Gegen Huoxue Tongluo liniment, which was applied after the surgical incision had healed.

Osteoarthritis granule (spleen and kidney deficiency type): oral 1 ~ 2 bags a day, with 150 ml warm water, once in the morning and once in the evening; the course of treatment was 4 weeks.
Duhuo Sanqi Xiaotong Granules: oral administration of 1-2 bags a day, warm boiled water, once in the morning and once in the evening ; the course of treatment was 4 weeks.
Gegen Huoxue Tongluo Liniment: Apply an appropriate amount of liniment to the affected part of the knee joint, and gently press until the liniment is completely absorbed. Three times a day.

The control group and the experimental group were treated with physical therapy.
Cold therapy, which is mainly used during the acute postoperative period (usually within 0–3 days after surgery). Each cold application should be strictly controlled at 10 minutes, with an interval of 1–2 hours, and repeated several times a day. Special attention should be paid to ensuring that the single cold application time should not exceed 12 minutes.
Heat therapy is applied after the acute inflammatory phase (usually starting 3–4 days after surgery), Each application lasts for 20–30 minutes and is applied two or three times a day.

For passive movement therapy, from postoperative days 0–7, the therapist performs the following steps. First, a continuous passive motion device is used – with the initial range of motion set at 0°–30° flexion, increasing this by 10° daily (aiming to reach over 90° by postoperative day 14) – twice a day for 30 minutes each time. This is combined with manual knee flexion and extension training. Here, the therapist fixes the distal end of the patient's femur and passively flexes the ankle joint, with 10–15 repetitions per set (three sets daily), stopping when the VAS score is ≥3 or joint swelling worsens. The therapist simultaneously performs patellar mobilisation, sliding 10 times in each of the up-down and left-right directions (holding for 5 seconds in each direction), twice a day.

Active exercise was also included. From days 1–7 after the operation, the training mainly focuses on lying-down exercises, including ankle pump exercises (maximally flexing and extending the ankle joint and contracting the calf muscles, 10 times per hour), isometric contractions of the quadriceps (placing a rolled towel under the knee, pressing the heel down to contract the anterior thigh muscles, holding for 5 seconds, 15 times per set, three sets per day) and straight leg raises (extending the knee and raising the leg 15–20 cm, 10 times per set, three sets per day). From days 8–21 after the operation, the training transitions to weight-bearing exercises, including sitting knee flexion sliding (keeping the heel on the bed and flexing the knee, with the healthy leg assisting in applying pressure, holding for 10 seconds, 10 times per set, three sets per day), mini squats (holding onto a walker and flexing the knee 15°–30° while maintaining an upright upper body, 10 seconds per time, three sets per day) and 10-cm step training (the healthy leg goes up first, followed by the operated leg, and the healthy leg goes down first), twice a day for 5 minutes each time. From days 22–28 after the operation, the focus shifts to functional reconstruction, including zero-resistance stationary bike training (starting at 5 minutes and increasing by 2 minutes each day), balance board standing (from both feet to one foot, with the knee slightly bent, 1 minute each time, five times per day) and chest-deep water walking (twice a day, 10 minutes each time).

Ultrasound therapy is mainly used in the subacute stage (e.g. 1–2 weeks after surgery). The application employs therapeutic ultrasound equipment, with a common frequency of 1 MHz (to provide deeper tissue penetration and act on the deep structures around the knee joint). In the initial stage, the pulse mode (with a duty cycle of 20%–50%) is often used to avoid overheating. Depending on the patient's tolerance and treatment response, this can be adjusted to the continuous mode. Each treatment lasts for 15–20 minutes, and is conducted 2–3 times per week.

Electrical stimulation (transcutaneous electrical nerve stimulation) : 30 minutes each time, 1–2 times a day.
Massage therapy (e.g. 1–2 weeks after surgery): Each session lasts for 15–20 minutes, and the frequency is adjusted according to the patient's condition.

What are the possible benefits and risks of participating?
Benefits: the application of TCM combined with physical therapy can significantly improve knee function (KSS), reduce postoperative pain (VAS score) and improve the sleep quality of patients (PSQI score)
Risks: Participants may experience symptoms such as nausea, vomiting, drowsiness, and chills.

Where is the study run from?
The First Affiliated Hospital of Heilongjiang University of Chinese Medicine, China.

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

Who is funding the study?
The Natural Science Foundation of Shandong Province, China.

Who is the main contact?
Shuren Wang, wangshuren_w87@163.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
Dr Shuren Wang

### Contact details
No. 26, Heping Road, Xiangfang District
Harbin, Heilongjiang
China
150040
+86 13904606969
wangshuren_w87@163.com


# Additional identifiers

### Natural Science Foundation of Shandong Province grant number
ZR202103020544

# Study information

### Scientific Title
Clinical efficacy and safety of traditional chinese medicine for knee arthroplasty recovery

### Study objectives
To evaluate the clinical efficacy and safety of traditional Chinese medicine (TCM) combined with physical therapy in patients undergoing knee arthroplasty.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 29/04/2025, First Affiliated Hospital of Heilongjiang University of Chinese Medicine (No. 26, Heping Road, Xiangfang District, Harbin, Heilongjiang, 150040, China; +86 0451-87967392; hljzylunli@163.com), ref: SDTHEC202504160

### Primary study design
Interventional

### Allocation
Randomized controlled trial

### Masking
Blinded (masking used)

### Control
Active

### Assignment
Parallel

### Purpose
Treatment

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
106 patients who underwent knee arthroplasty

### Interventions
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## Intervention Type
Drug/Device

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Osteoarthritis particles, Duhuo Sanqi Xiaotong granules, Gegen Huoxue Tongluo liniment, celecoxib, diclofenac sodium

## Primary outcome(s)
1. Knee joint function measured using the Knee Score (KSS) at 1 month post-surgery

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## Key secondary outcome(s))
1. Postoperative pain intensity measured using the Visual Analogue Scale (VAS) at 1 month post-surgery

2. Sleep quality measured using the Sleep Quality Index (PSQI) at 1 month post-surgery

3. Incidence of postoperative complications measured using measured using data collected from patient medical records at at one time point

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## Completion date
30/06/2024

# Eligibility

### Key inclusion criteria
1. Diagnosis is knee osteoarthritis, rheumatoid arthritis or knee dysfunction caused by trauma, in line with the indications of knee arthroplasty
2. Total knee arthroplasty or partial knee arthroplasty is planned
3. preoperative physical condition was good, with no serious medical diseases (e.g. heart disease, diabetes, liver or kidney dysfunction)
4. Patients or their legal guardians signed informed consent forms and agreed to participate in this study
5. Patients with appropriate psychological state, with no serious mental illness or cognitive impairment
6. Patients diagnosed with spleen-kidney deficiency syndrome (manifested as soreness and weakness of waist and knees, aversion to cold limbs, frequent nocturia, pale tongue with white coating, deep and thready pulse) confirmed by two senior TCM physicians

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
59 years

### Upper age limit
69 years

### Sex
All

### Total final enrolment
106

### Key exclusion criteria
1. With severe complications, such as uncontrolled hypertension, heart disease or other chronic diseases, that may affect postoperative recovery
2. With surgical contraindications such as infection around the knee joint and tumour
3. With a history of allergies to the TCM ingredients or anaesthetics involved in the study
4. Who have undergone other joint or major surgery in the last 6 months
5. With chronic pain syndrome or multiple pain disorders
6. Who were pregnant or lactating
7. Who could not follow the doctor’s instructions due to psychological factors or other reasons, or patients who may affect the results of the study
8. With damp-heat stasis syndrome (red tongue with yellow greasy coating, rapid pulse) due to potential aggravation by warming herbs in the formula

**Date of first enrolment**
01/03/2023

**Date of final enrolment**
31/12/2023

# Locations

**Countries of recruitment**
China

**Study participating centre**
**The First Affiliated Hospital of Heilongjiang University of Chinese Medicine**
No. 26, Heping Road, Xiangfang District, Harbin
Harbin, Heilongjiang
China
150040

# Sponsor information

**Organisation**
First Affiliated Hospital of Heilongjiang University of Chinese Medicine

**ROR**
https://ror.org/01c0exk17

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Natural Science Foundation of Shandong Province

**Alternative Name(s)**
Shandong Provincial Natural Science Foundation, Shandong Natural Science Foundation, Natural Science Foundation of Shandong, Shandong Province Natural Science Foundation,

**Funding Body Type**
Government organisation

**Funding Body Subtype**

Local government

**Location**
China

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not expected to be made available