ISRCTN75218899 https://doi.org/10.1186/ISRCTN75218899

Acupuncture at the P6 acupoint for pain control in teenagers after triple repair surgery of patellar dislocation

Submission date	Recruitment status	[X] Prospectively registered
06/05/2024	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/05/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/05/2024	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The triple surgery of adolescent patellar dislocation (TSAPD) can preferably correct patellar dislocation (a dislocated kneecap), but pain management after surgery is challenging, especially for teenagers whose medication is restricted. This study will investigate the effectiveness of motion pain control with an Indwelling acupuncture needle added to standard therapy in teenagers after triple surgery of TSAPD.

Who can participate?
Patients aged 13-18 years undergoing TSAPD

What does the study involve?
Patients will be randomly allocated to an experimental group or a control group. The experimental group will be treated with real acupuncture needles while the control group will be treated with false needles on the same points. The needles will be indwelling for 72 hours. Pain is measured at 24, 48, and 72 hours after rehabilitation exercise. The total amount of additional analgesics used, the rate of analgesic side effects, the satisfaction of patients with postoperative analgesia, and quality of life will be recorded.

What are the possible benefits and risks of participating?
The patients may have better pain control after surgery, and this study will also help determine which treatments can be used more safely and effectively with similar conditions. There are few adverse reactions, such as local skin allergy, mild pain and discomfort during the experiment.

Where is the study run from?
West China Hospital of Sichuan University (China)

When is the study starting and how long is it expected to run for?
August 2023 to August 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Pengcheng Li, 16699411@qq.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Ms Pengcheng Li

Contact details
No.37, Guoxue Lane
Wuhou District
Chengdu City
China
610041
+86 (0)18980601911
16699411@qq.com

Additional identifiers

Study information

Scientific Title
Acupuncture at the P6 acupoint for pain control in teenagers after triple repair operation of patellar dislocation: a randomized, placebo-controlled, double-blind trial

Study objectives
Using an indwelling press needle at Neiguan point can improve the pain intensity or reduce the amount of analgesic drugs during resting and rehabilitation exercises after triple repair operation of patellar dislocation in adolescents under general anesthesia.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/09/2023, Biomedical Ethics Review Committee of West China Hospital, Sichuan University (Room 412~413, Laobajiao, No.37, Guoxue Lane, Wuhou District, Chengdu, 610044, China; +86 (0)28 65423237; huaxilunli@163.com), ref: 20231530

Study design
Singal-center interventional double-blind placebo-controlled randomized trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Pain control of patellar dislocation patients undergoing triple repair surgery

Interventions
Patients will be randomly allocated to an experimental group and a control group using a random number table. An indwelling press needle (0.2 x 1.5 mm, Pyonex, Seirin Corporation, Shizuoka, Japan) will be used as an acupoint intervention in the experiment group. Bilateral Neiguan points are chosen as the acupoints. The experimental group will use real needles while the control group use false needles on the same points (false indwelling acupuncture). The needles will be indwelling for 72 hours.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain intensity measured using visual analogue score (VAS) at 24 h, 48 h, and 72 h after the rehabilitation exercise

Key secondary outcome(s))
1. Intensity of maximum and minimum resting pain measured using VAS at 24 h, 48 h, 72 h after surgery
2. Total amount of additional analgesics used: the researchers will record the total amount of different drugs according to the doctor's order after surgery for 72 hours.
3. Rate of analgesic side effects: if the patient displays any analgesic side effect symptoms, it will be recorded as "once", such as vomiting once or twice, etc.
4. Satisfaction of patients with postoperative analgesia measured using a visual analogue scale at discharge
5. Quality of life items disturbed by pain, measured by asking and recording the patients' subjective cognition every morning until the press needle is removed
6. Successful blinding of patients: a special researcher will ask the question "Do you know which group are you in?" when they finish data collection. The researcher judges whether the blinding is a success or not according to the answer.

Completion date
10/08/2028

Eligibility

Key inclusion criteria
1. Adolescent patients aged 13-18 years
2. Patients who underwent this procedure for the first time
3. Patients with unilateral surgery
4. Junior high school or above
5. Patients undergoing general anesthesia
6. No previous history of opioid and psychotropic medication
7. No previous history of smoking or alcoholism
8. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Changes in surgical methods for various reasons
2. Patients with combined cardiovascular and cerebrovascular disease
3. Patients with mental cognitive impairment or a history of mental illness
4. Skin damage in the needle prick site or patients with infection
5. Femoral nerve block in anesthetized patients
6. Patients with forced braking for various causes
7. Patients who cannot adhere to all treatment and follow-up

Date of first enrolment
15/05/2024

Date of final enrolment
15/05/2028

Locations

Countries of recruitment
China

Study participating centre
West China Hospital, Sichuan University
No.37, Guoxue Alley
Chengdu, Sichuan
China
610044

Sponsor information

Organisation
West China Hospital of Sichuan University

ROR
https://ror.org/007mrxy13

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 analysed during the current study will be available upon request from Li Pengcheng (16699411@qq.com)

IPD sharing plan summary
Available on request