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Efficacy and safety of Tibetan medicine Qingpeng ointment for patients with acute gouty arthritis

Submission date
15/01/2021

Recruitment status
No longer recruiting

Registration date
25/01/2021

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gout is a type of arthritis where crystals form inside and around joints, causing pain, redness and swelling. Treatments for acute gouty arthritis have included non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and colchicine for the control of pain and inflammation. Qingpeng ointment is a marketed Tibetan patent medicine for external use which is composed of Herba Oxytropis Falcatae, Rhei Spiciforme Randix, Radix Aconiti Flavi Et Penduli, Chebulae Fructus, etc, and has the effects of promoting blood circulation, removing blood stasis, reducing swelling and pain, and can be used to treat swelling and pain of muscles and joints. Previous clinical studies showed that Qingpeng ointment could relieve pain, swelling, redness and dysfunction of joints in patients with acute gouty arthritis. This study aims to evaluate the effectiveness and safety of Qingpeng ointment for acute gouty arthritis.

Who can participate?
Patients aged between 18 and 65 with acute gouty arthritis

What does the study involve?
Participants will be randomly divided into two groups (treatment group and control group). Patients in the treatment group will be treated with Qingpeng ointment and patients in the control group will be treated with placebo (dummy ointment). Patients in both groups will be given diclofenac sodium sustained-release tablets (DSSRT) to take when the pain is intolerable. The degree of joint pain, swelling, redness and motility, and level of C-reactive protein and blood uric acid will be used to evaluate the effectiveness of the ointment. All patients will be treated for 1 week and followed up for 1 week.

What are the possible benefits and risks of participating?
The possible benefits of this study include relief of joint pain, redness and swelling, and improvement in joint mobility. The possible risks include skin irritation, such as skin itching, rashes and blisters.

Where is the study run from?
1. Fangshan Hospital, Beijing University of Chinese Medicine, Beijing (China)
2. The Second Affiliated Hospital of Zhejiang Chinese Medical University, Hangzhou (China)
3. Liuzhou People's Hospital, Liuzhou city, Guangxi Zhuang Autonomous Region (China)

When is the study starting and how long is it expected to run for?
May 2020 to January 2022

Who is funding the study?
Tibet Cheezheng Tibetan Medicine Co., Ltd (China)

Who is the main contact?
Prof. Jianping Liu
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
202008v3.0

Study information

Scientific Title
Efficacy and safety of Qingpeng ointment for acute gouty arthritis: a multi-center, randomized, double-blind, placebo-controlled trial

Acronym
QAGAR

Study objectives
1. Qingpeng ointment can relieve the joint pain of patients with acute gouty arthritis.
2. Qingpeng ointment can reduce the joint swelling of patients with acute gouty arthritis.
3. Qingpeng ointment can improve the joint mobility in patients with acute gouty arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2020, Ethics Committee of Fangshan Hospital, Beijing University of Chinese Medicine (151 Chengguan South Street, Fangshan District, Beijing, China; +86 (0)10 89321886; email not available), ref: FZY LK-2020-015

Primary study design
Interventional

Study design
Multi-center randomized double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute gouty arthritis

Interventions
Patients who meet the inclusion and exclusion criteria will be randomly divided into the treatment group and control group, with 103 patients in each group. The random sequence is generated using SAS statistical software. Pharmacy-controlled randomization method will be used to achieve allocation concealment.

Before treatment, general physical examination and laboratory tests (blood and urine routine, liver and kidney function, blood uric acid, C-reactive protein) will be conducted, degree of joint pain, swelling, redness and mobility will be scored, and width and thickness of the affected joints will be measured.

During the treatment period, patients in the treatment group will be treated with Qingpeng ointment, and patients in the control group will be treated with placebo. Patients in both groups will be given Diclofenac Sodium Sustained-Release Tablets (DSSRT) as rescue medicine. Qingpeng ointment and placebo will be used on affected joints twice a day. The dosage is that the ointment can cover the surface of affected joints, and the thickness is 0.3-0.5 cm. The applied part needs to be massaged gently until the ointment is totally absorbed by the skin. DSSRT will be taken only when the VAS score of joint pain is ≥7 (scale of 0 to 10). The recommended dose is one tablet per time, once daily, and the maximum dose is one tablet per time, twice a day. The width and thickness of joints will be measured every day, and the degree of joint pain, swelling, redness and mobility will be scored every day. The course of treatment is 7 days.

After treatment, the blood uric acid and C-reactive protein will be tested, the degree of joint pain, swelling, redness and mobility will be scored, the width and thickness of joints will be measured, and the remaining amount of DSSRT will be recorded. Patients will be followed up for 1 week.

Intervention Type
Other

Primary outcome(s)
1. Joint pain measured using a visual analogue scale (VAS, 0-10 points) at baseline, every day during treatment, and after treatment
2. Joint swelling:
2.1. The width and thickness of each affected joint are measured using vernier calipers (brand: Ruineng, model: NR0139) at baseline, every day during treatment, and after treatment
2.2. Joint swelling measured using a visual analogue scale (VAS, 0-10 points) at baseline, every day during treatment, and after treatment

Key secondary outcome(s)
1. Joint mobility measured using a 0-4 point scale (0=the mobility is normal, and is not restricted; 1=the mobility is slightly restricted, but normal activities can still be performed; 2=the mobility is moderately restricted, patient is unable to perform general activities, and is able to take care of self daily life; 3=the mobility is severely restricted, pain is unbearable when the joint moves, patient is unable to take care of self daily life; 4=the joint is unable to move), at baseline, every day during treatment, and after treatment
2. Joint redness measured using a 0-3 point scale (0=the skin color is normal; 1=the skin is slightly red; 2=the skin is obviously red; 3=the skin is dark red), at baseline, every day during treatment, and after treatment
3. C-reactive protein measured from a blood sample taken at baseline and after 7 days of treatment
4. Serum uric acid measured from a blood sample taken at baseline and after 7 days of treatment
5. Remaining amount of rescue medicine recorded after 7 days of treatment

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Patients who meet the ACR (American College of Rheumatology)/EULAR (European League Against Rheumatism) gout classification criteria
2. Patients with joint pain intensity score (VAS, 0-10 points) ≥3 points
3. Patients with an acute flare of gout, the time from the onset to the visit to hospital should not exceed 1 week
4. Patients aged between 18 to 65 years old
5. Patients who are volunteer to participate in the study and sign the informed consent

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
203

Key exclusion criteria
1. Patients who also suffer from other types of arthritis
2. Patients who are allergic to the study drugs (Qingpeng Ointment, DSSRT)
3. Patients suffering from severe cardiovascular, cerebrovascular, liver, and kidney diseases
4. Patients suffering from mental diseases and senile dementia
5. Women during pregnancy and lactation
6. Patients with skin ulceration at the affected joint(s)
7. Patients who have newly added uric acid-lowering drugs for any reason in the past week
8. Patients who participate in other clinical trials at the same time

Date of first enrolment
01/03/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
China

Study participating centre
Fangshan Hospital, Beijing University of Chinese Medicine
No. 4, Chengguan Baojian Road
Fangshan District
Beijing
China
102499

Study participating centre
The Second Affiliated Hospital of Zhejiang Chinese Medical University
No. 318, Chaowang Road
Gongshu District

Hangzhou
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Study participating centre
Liuzhou People's Hospital
No. 8 Wenchang Road
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545006

Sponsor information

Organisation
Beijing University of Chinese Medicine

ROR
https://ror.org/05damtm70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tibet Cheezheng Tibetan Medicine Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available based on the contract with the company.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/01/2024	08/01/2024	Yes	No

Protocol article	12/05/2022	16/05/2022	Yes	No