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Chuanhu anti-gout mixture in therapy of acute gouty arthritis

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Chuanhu anti-gout mixture has been used for many years for treating gout in Chinese Traditional Medicine (TCM), while current standards for treatments for acute gouty arthritis (such as anti-inflammatory drugs [NSAIDs], colchicine and corticosteroids) were either less effective or had serious side-effects. The present study was designed to test the effectiveness of Chuanhu anti-gout mixture for therapy of acute gouty arthritis compared to colchicines.

Who can participate?
Adults with a new clinical diagnosis of gout and onset of the disease duration less than 48 hours were eligible to participate.

What does the study involve?
The participants were randomly allocated to one of the two groups:
Chuanhu group: to receive Chuanhu anti-gout mixture orally daily and placebo (dummy).
Colchicine group: to receive Colchicine 1 piece orally two times daily, for 3 days, later change to once daily, and placebo (dummy).
All of the patients were treated with etoricoxib 60 mg once daily orally to relieve pain of the affected joints for 10 days.

What are the possible benefits and risks of participating?
Chuanhu anti-gout mixture might be effective for therapy of acute gouty arthritis, and have fewer side-effects compared to colchicine. The possible risks include the adverse reactions pain, swelling and activity limitation of the joint, together with injury/damage to the liver and kidney.

Where is the study run from?
The study was run in the Affiliated Hospital of Qingdao University Medical College, Qingdao, China.

When is the study starting and how long is it expected to run for?
The study started in November 2011 and ran until November 2012.

Who is funding the study?
The study was founded by the Affiliated Hospital of Qingdao University Medical College and National Natural Sciences Foundation of China.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Chuanhu anti-gout mixture versus Colchicine for acute gouty arthritis: a randomized, double-blind, double-dummy, non-inferiority trial

Study objectives
Chuanhu anti-gout mixture has been used for many years in Chinese Traditional Medicine (TCM), and may be an effective treatment for acute gouty arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by Qingdao Universitys ethics committee, Nov 1st, 2010

Study design
Randomized double-blind double-dummy non-inferiority trial

Primary study design

Interventional

Study type(s)
Treatment

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

Interventions
Following screening, eligible patients were randomized (1:1) to two groups:
1. Chuanhu group, to receive Chuanhu anti-gout mixture 250ml orally daily and placebo (looks like colchicine).
2. Colchicine group, to receive Colchicine 1 piece orally (0.5mg per piece), 2 times daily, for 3 days, later change to once daily, and placebo (looks like Chuanhu anti-gout mixture).
All of the patients were treated with etoricoxib 60mg once daily orally to relieve pain of the affected joints for 10 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chuanhu, Colchicine

Primary outcome(s)
The recurrence rate within three months of these selected patients after 10 days treatment

Key secondary outcome(s))
1. The changes of white blood cells and C-reactive protein (CRP).
White blood cells were measured at North West University Nutrition laboratory using an AcT 5diff Cap Pierce Hematology Analyzer, and CRP was measured by immunoturbidimetric test, at the baseline and after 10days of follow up.
2. Adverse reactions, the score of pain, swelling, and activity limitation of the joint (1-4 point scale, for absent, mild, moderate, or severe, respectively), were recorded in the patient diary, and biochemical indicators were detected.

Completion date
01/11/2012

Eligibility

Key inclusion criteria
Adults >=18 year old, either sex, with a new clinical diagnosis of gout according to the 1977 American College of Rheumatology classification criteria and onset of the disease duration less than 48 hours were eligible to participate.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
176

Key exclusion criteria
1. Secondary gout, such as rheumatoid arthritis, septic arthritis, traumatic arthritis, etc
2. Gout in intermittent period or with tophi
3. Taking the following drugs: diuretics, pyrazinamide, aspirin, etc
4. Pregnancy, breast-feeding women
5. Cardiovascular and cerebral vascular disease, and severe trauma or underwent surgery
6. Severe infections
7. Hepatobiliary disease or whose ALT and AST were two times higher than upper limit of normal
8. The serum creatinine greater than the upper limit of normal
9. Severe chronic gastrointestinal disease
10. Hematological diseases or endocrine system diseases
11. Undergoing cancer treatment
12. Receiving steroid therapy
13. Allergic to those known ingredients in Chuanhu anti-gout mixture.

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
China

Study participating centre
10 Youanmenwai Xitoutiao
Beijing
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Sponsor information

Organisation
The Affiliated Hospital of Medical College Qingdao University (China)

ROR
https://ror.org/026e9yy16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Affiliated Hospital of Qingdao University Medical College (China)

Funder Name
The study was in part supported by National Natural Science Foundation of China (81001281)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/06/2014	17/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes