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Compare the combination of traditional Chinese medicine (Qingre Huashi Quyu) and mesalazine with mesalazine for the treatment of ulcerative colitis.

Submission date
25/04/2019

Recruitment status
No longer recruiting

Registration date
07/05/2019

Overall study status
Completed

Last Edited
29/10/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a non-specific inflammation of the intestine, with abdominal pain, diarrhea, mucus pus and bloody stools and urgency as the main clinical manifestations. Because the cause is unknown, difficult to cure, easy to progress to a cancer, it has been listed as a difficult disease by the World Health Organization (WHO). This study aims to determine whether the Qingrehuashiquyu recipe might help those UC patients, as previous studies have shown it may be beneficial.

Who can participate?
Adults aged 18-65 who have been diagnosed by their doctors as having ulcerative colitis.

What does the study involve?
Participants are randomly allocated to one of two groups:
1. Qingrehuashiquyu recipe 200ml, taken orally two times per day and mesalazine 0.25g, taken orally four times per day for 12 weeks
2. Mesalazine 0.25gtaken orally four times per day for 12 weeks
Following completion of this 8 week period, there is another 12 week follow-up period.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the Qingrehuashiquyu recipe and mesalazine may improve symptoms of patients, although this cannot be guaranteed. The possible risks of participating are that the treatment may cause side effects including epigastric discomfort, nausea, headache and dizziness, although this is unlikely.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University, China

When is the study starting and how long is it expected to run for?
June 2018 to August 2022

Who is funding the study?
Beijing municipal commission of science and technology

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2019-02-25

Study information

Scientific Title
Efficacy of Qingrehuashiquyu recipe on ulcerative colitis: a randomized controlled study

Study objectives

Combination of Qingrehuashiquyu recipe and mesalazine is more effective in the treatment of ulcerative colitis than mesalazine used alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2019, Ethics Committee of Beijing Chinese Medicine Hospital affiliated to Capital Medical University (Beijing Hospital of Traditional Chinese Medicine Capital Medical University No. 23 Art Museum Houjie Street Dongcheng District; ecbjtcm@126.com; +8601052171516), ref: 2019BL02-007-01

Study design
Interventional single-center randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
Participants are randomly allocated to one of two groups using SAS9.10 software:
1. Qingrehuashiquyu recipe 200ml, taken orally two times per day and mesalazine 0.25gtaken orally four times per day for 12 weeks
2. Mesalazine 0.25gtaken orally four times per day for 12 weeks
Following completion of this 12 week period, there is another 12 week follow-up period.

Clinical symptoms data and samples including blood, stool and colonic mucosa will be collected by clinicians. Blood will be collected by drawing blood of centrifugal vein. Stool will be collected by specimen box. Colonic mucosa will be collected by electronic endoscope.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Qingrehuashi quyu recipe

Primary outcome(s)
Current primary outcome measure as of 29/10/2021:
Mayo Activity Index, assessed at baseline and 12 weeks

Previous primary outcome measure:
Mucosal histology score measured using Geboes index, assessed at baseline and 12 weeks.

Key secondary outcome(s))
Current secondary outcome measures as of 29/10/2021:
1. Mucosal histology score measured using Geboes index, assessed at baseline and 12 weeks
2. Traditional Chinese Medicine syndromes of UC score, assessed at baseline,4,8 and 12weeks
3. Fecal occult blood test, erythrocyte sedimentation rate, C-reactive protein, fecal calprotectin at baseline and 12weeks
4. Detection of intestinal apoptosis at baseline and 12 weeks
5. Detection of intestinal flora at baseline and 12 weeks
6. Detection of intestinal nitric oxide at baseline and 12 weeks
7. Inflammatory bowel disease quality of life scale at baseline and 12 weeks

Previous secondary outcome measures:
1. Mayo Activity Index, assessed at baseline and 12 weeks
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7. Inflammatory bowel disease quality of life scale at baseline and 12 weeks

Completion date
01/08/2022

Eligibility

Key inclusion criteria
1. The diagnosis of ulcerative colitis is active, and the clinical severity is mild to moderate.
2. Meeting the Traditional Chinese Medicine syndrome of large intestinal damp-heat criteria.
3. The age is between 18 and 65 years old, and gender is not limited.
4. The patient signs informed consent. The process of obtaining informed consent should be in accordance with GCP regulations.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. The type of ulcerative colitis is acute fulminant, and the severity of the condition is severe.
2. Infectious colitis such as bacillary dysentery, amoebic sputum, chronic schistosomiasis, intestinal tuberculosis, and patients with Crohn's colitis, ischemic enteritis, and radiation enteritis.
3. Patients with serious complications such as local stenosis, intestinal obstruction, intestinal perforation, rectal polyps, toxic colonic dilatation, colon cancer, rectal cancer and anal disease.
4. Pregnant and lactating women
5. Those with severe primary heart, liver, lung, kidney, blood or serious diseases that affect their survival.
6. Disabled patients prescribed by law.
7. Suspected or indeed had a history of alcohol and drug abuse.
8. Poor compliance or any other reason the researchers believe may not be appropriate to participate in this trial.
9. Allergic constitution or known to be allergic to the drug used in this trial.
10. Patients who are participating in other drug clinical trials.

Date of first enrolment
20/04/2019

Date of final enrolment
01/05/2021

Locations

Countries of recruitment
China

Study participating centre
Digestive Disease Center
Beijing Hospital of Traditional Chinese Medicine
Capital Medical University
No. 23
Art Museum Houjie Street
Dongcheng District
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Sponsor information

Organisation
Beijing Municipal Science & Technology Commission

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission

Alternative Name(s)
Science and Technology Commission of Beijing Municipality, Beijing Municipal Science & Technology Commission, Adminitrative Commission of Zhongguancun Science Park, Beijing Municipal Science and Technology Commission, Beijing Municipal Science & Technology Commission, , ,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes