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A Chinese herbal medicine (Xilei-san) for mild /moderate ulcerative proctitis

Submission date	Recruitment status	[ ] Prospectively registered
18/11/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/12/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/09/2016	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ulcerative colitis is a long-term condition where the colon and rectum become inflamed. The colon is the large intestine (bowel), and the rectum is the end of the bowel where stools are stored. Corticosteroids such as dexamethasone are a type of medication used to reduce the inflammation. They can be administered orally (by mouth) or through a suppository or enema (into the rectum). Xilei-san is a traditional Chinese herbal medicine. Recently a study showed that Xilei-san was effective at treating ulcerative proctitis (a mild form of ulcerative colitis). The aim of this study is to compare a rectal Xilei-san enema with a conventional steroid enema in the treatment of patients with mild or moderate ulcerative proctitis.

Who can participate?
Patients aged 18 to 80 with ulcerative proctitis

What does the study involve?
Participants undergo a colonoscopy, where a flexible tube containing a camera is used to examine the colon and assess the severity of their condition. Participants are then randomly allocated to be treated with either dexamethasone or Xilei-San enemas. They are assessed again at week 4, 8 and 20.

What are the possible benefits and risks of participating?
Participants may benefit from a decrease in the severity of their condition. Participants may suffer from an allergic reaction, and the symptoms are joint pain, muscle pain, fever, rash and discomfort.

Where is the study run from?
First Affiliated Hospital of Zhengzhou University (China)

When is the study starting and how long is it expected to run for?
August 2010 to August 2011

Who is funding the study?
1. Research fund for the Doctoral Program of Higher Education of China (China)
2. The Youth Innovation Fund of the First Affiliated Hospital of Zhengzhou University (China)

Who is the main contact?
Dr Fangbin Zhang

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Chinese herbal medicine (Xilei-san) for mild/moderate ulcerative proctitis: a randomised, placebo controlled study

Study objectives
Xilei-san enema is effective in the treatment of mild to moderate ulcerative proctitis (UP)

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Affiliated Hospital of Zhengzhou University, 01/08/2010, ref: 20100801GS-7

Study design
Randomised placebo-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Mild or moderate ulcerative proctitis

Interventions
Dexamethasone was formulated as 5 mg/60 ml and Xilei-San as 1000 mg/60 ml (Beijing Tong Ren Tang Ltd., Co., Beijing, China). Patients were instructed to take the formulation as enema once a day for 4 weeks and monitored the usage of drug and the compliance of patients by weekly clinic visit. Only those patients attaining clinical response were recruited in the second stage treatment.

In the second stage treatment, dexamethasone was formulated as 2 mg/60 ml. Patients in group I were received rectal preparation once a day for 2 weeks, followed by once every 2 days for 1 week, and once every 3 days for 1 week, then discontinue the dexamethasone therapy for 12 weeks. Patients in group II were received the same dosage of rectal Xilei-San preparation once a day for 4 weeks, then discontinued the Xilei-San therapy for 12 weeks.

All patients were assigned to be administered oral mesalazine 1000 mg (Etiasa, Ferring, Ipsen, Germany) 3 times a day as the foundation treatment and not allowed to use other medicine during the whole trial.

Patients were enrolled consecutively following a medical evaluation of the initial clinical and endoscopic severity of the condition using full colonoscopy. They were evaluated at inclusion, and at week 4, 8 and 20. Colonoscopy was done by the same gastroenterologist and all biopsy specimens were studied by the same experienced pathologist.

Clinical severity of the disease was determined according to the refined criteria of Marteau considering the major clinical manifestations of mild to moderate UP was rectal bleeding, but not obvious systemic symptoms. Remission was defined as a score = 0, and last 3 times fecal occult blood test was negative within the last 1 week. Improvement was defined as a decrease in the score by 2 points from baseline. Partial improvement was defined as a decrease in the score by 2 points from baseline and sum score > 2 points. Non-improvement was defined as a decrease in the score by < 2 points from baseline or an increase in the score. Clinical relapse was evaluated in patients attaining clinical response and remission at week 8, and was defined as occurrence of bloody stools and positive fecal occult blood test >2 times in last 12 weeks.

Endoscopic severity of the disease was determined according to mucosa appearance: 0 = normal; 1 = erythema, reduced capillary network, mild friability, minimal granularity; 2 = friability, marked erythema, no vascularisation, erosions, pus; 3 = ulceration, spontaneous bleeding, pus; Three categories for endoscopic response were: remission, a score = 0; response, a decrease in the score by 1 point from baseline; no response, similar or aggravated endoscopic finding compared with baseline.

Histological severity of the disease was determined according to the criteria of Truelove & Richards.: 0 = no significant Inflammation; 1 = mild inflammation; 2 = moderate inflammation; 3 = severe inflammation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Herbal medicine (Xilei-san)

Primary outcome measure
Clinical remission rate at week 4

Secondary outcome measures
1. Clinical and endoscopic remission rates at week 8
2. Clinical relapse rates at week 20
3. Adverse events were assessed at week 4, 8 and 20

Overall study start date
01/08/2011

Completion date
01/08/2011

Eligibility

Key inclusion criteria
Patients between the ages of 18 and 80 years were eligible to participate if they had previously established UP with mild to moderate exacerbation at least 7 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Xilei-san group: 18; Conventional steroid group: 17

Key exclusion criteria
1. Patients receiving 5-aminosalicylic acid and/or immunosuppressive agents in 7 days prior to entry into the trial, except those suffering symptomatic relapse during maintenance treatment of oral 5-aminosalicylic acid (5-ASA) preparations
2. Patients currently or recently receiving any oral or rectal steroid preparation
3. Patients having any episode of drug allergy and
4. Pregnant or lactating women

Date of first enrolment
01/08/2011

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
China

Study participating centre
Zhengzhou University
Zhengzhou
China
450052

Sponsor information

Organisation
Zhengzhou University (China)

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40 Daxue Road
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Sponsor type
University/education

ROR

https://ror.org/04ypx8c21

Funder(s)

Funder type
University/education

Funder Name
Research fund for the Doctoral Program of Higher Education of China (China)

Funder Name
The Youth Innovation Fund of the First Affiliated Hospital of Zhengzhou University (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration