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Comparison of the effect of iguratimod and hydroxychloroquine in the treatment of primary Sjögren's syndrome

Submission date
12/05/2025

Recruitment status
No longer recruiting

Registration date
15/05/2025

Overall study status
Completed

Last Edited
14/05/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Several studies have shown that iguratimod (IGU) has achieved certain efficacy in the treatment of primary Sjögren's syndrome (pSS). However, there is no study examining whether IGU affects regulatory B cells (Bregs) in patients with pSS. The purpose of this study is to evaluate the effect of IGU and hydroxychloroquine (HCQ) in the treatment of pSS and to analyse the influence of these two drugs on Bregs in peripheral blood.

Who can participate?
Patients with pSS aged 18-65 years

What does the study involve?
Treatment in the IGU group was as follows: ≤10 mg of prednisone per day, 25 mg of IGU twice a day; treatment in the HCQ group was as follows: ≤10 mg of prednisone per day, 0.2 g of HCQ twice a day. Questionnaires were used to assess disease activity.

What are the possible benefits and risks of participating?
Both IGU and HCQ may reduce the disease activity and fatigue score of patients with pSS. IGU may be superior to HCQ in reducing IgG levels.
This study does not involve any risks.

Where is the study run from?
Mianyang Central Hospital, China

When is the study starting and how long is it expected to run for?
December 2029 to June 2023

Who is funding the study?
1. Guangzhou Pukang Charitable Foundation
2. The Incubation Project of Mianyang Central Hospital

Who is the main contact?
Jing Yang, yangjing_2025yj@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PK-CF-2020-Z-1231, 2022FH006

Study information

Scientific Title
Comparison of the effect of iguratimod and hydroxychloroquine on regulatory B cells in the treatment of primary Sjögren's syndrome

Study objectives
Iguratimod may be more effective than hydroxychloroquine in the treatment of primary Sjögren's syndrome

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 29/12/2020, Ethic Committee of the MianYang Central Hospital (No. 12, Changjia Lane, Jingzhong Street, Mianyang, 621000, China; +86 0816-2239224; myszxyygcp@163.com), ref: S-2020-048

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients with primary Sjögren's syndrome

Interventions
The patients were randomly assigned to an iguratimod (IGU) group (n = 30) or a hydroxychloroquine (HCQ) group (n = 30) at a ratio of 1:1. All the patients were allowed to receive <0 mg of prednisone per day and vitamin D and calcium for 24 weeks to prevent osteoporosis; 25 mg of IGU was administered orally twice a day in the IGU group, and 0.2 g of HCQ was administered orally twice a day in the HCQ group. Treatment lasts 24 weeks. Follow-up evaluation and records were performed after treatment.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Iguratimod, hydroxychloroquine

Primary outcome measure
The following primary outcome measures were assessed at baseline and week 24:
1. Disease activity was measured using the EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) and the EULAR Sjögren's Syndrome Patient-Reported Index (ESSPRI)
2. Patient global assessment was measured using a 10-cm Visual Analogue Scale (VAS)

3. Fatigue degree was measured using the Functional Assessment of Chronic Illness Therapy (FACIT) questionnaire

Secondary outcome measures
Clinical and laboratory variables B lymphocytes and Bregs (CD19+ CD24 hiCD38hi, CD19+ CD24+ CD27+ and CD19+ CD5+ CD1d+ B cells) were measured using flow cytometric at baseline and week 24

Overall study start date
29/12/2020

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Aged 18–65 years
2. No glucocorticoids, immunosuppressants or biological agents within 3 months before baseline
3. Consent to contraception during the trial and within 3 months after the end of the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Patients with other immune system diseases, such as autoimmune liver disease, RA, systemic lupus erythematosus, scleroderma, myositis or Hashimoto's thyroiditis
2. Patients with serious organ involvement, such as severe pericardial effusion (echocardiography showing pericardial effusion thickness >10 mm), pulmonary interstitial lesions (high-resolution computed tomography showing ground-glass opacity or honeycomb lung), renal tubular acidosis (serum bicarbonate level >30 mmol/L and a urine ph value persistently >6.0) or atrophic gastritis (endoscopy showing gastric mucosal atrophy)

3. Patients with underlying cardiac, pulmonary, renal, gastrointestinal or metabolic conditions
4. Patients with chronic or latent infectious diseases or a history of malignancy, mental diseases or alcohol abuse
5. Pregnant and lactating women; patients with the following abnormal indicators – haemoglobin ≤90 g/L, platelet count <100 × 10^9/L, white blood cell count <3.0 × 10^9/L or >14 × 10^9/L, estimated glomerular filtration rate ≤45 ml/min/1.73 m^2, total bilirubin >1.5 × upper limit of normal (ULN), aspartate aminotransferase and alanine aminotransferase both >1.5 × ULN

Date of first enrolment
30/12/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre
Mianyang Central Hospital
No. 12, Changjia Lane, Jingzhong Street
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Sponsor information

Organisation
Mianyang Central Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.myzxyy.com/

ROR
https://ror.org/00s528j33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guangzhou Pukang Charitable Foundation

Funder Name
The Incubation Project of Mianyang Central Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy reasons.

IPD sharing plan summary
Not expected to be made available