

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

Submission date 12/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/05/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Several studies have shown that igratimod (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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment, Efficacy

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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Iguratimod, hydroxychloroquine

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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 $< 100 \times 10^9$ /L, white blood cell count $< 3.0 \times 10^9$ /L or $> 14 \times 10^9$ /L, estimated glomerular filtration rate ≤ 45 ml/min/1.73 m², total bilirubin $> 1.5 \times$ upper limit of normal (ULN), aspartate aminotransferase and alanine aminotransferase both $> 1.5 \times$ 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

Mianyang

China

621000

Sponsor information

Organisation

Mianyang Central Hospital

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

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

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