

# A randomised, double-blinded clinical study of LC for systemic lupus erythematosus patients

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>18/01/2008   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>11/04/2008 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>11/01/2017       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input checked="" type="checkbox"/> Results          |
|                                        |                                                       | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
DOH96-TD-I-111-006

## Study information

**Scientific Title**  
Double-blind, randomised, placebo-controlled pilot study of LC in systemic lupus erythematosus

**Acronym**

## **Study objectives**

LC, a mixture of two traditional Chinese herbal formulas, has been used for treatment of various disorders attributed to inflammation, including rheumatoid arthritis, herpes zoster, psoriasis, etc. Since immunopathological abnormalities usually occur in lupus mice and humans, we will evaluate the efficacy and safety of Chinese formula LC for the treatment of SLE patients.

## **Hypothesis:**

Under conventional therapy, taking TCM formula LC would be beneficial to the quality of life (QOL) and/or disease activity of SLE patients better than patients receiving placebo.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Institutional Review Board/Chang Gung Memorial Hospital (IRB/CGMH), 11/11/2007, ref: 96-1117C

## **Primary study design**

Interventional

## **Study design**

Double-blind randomised placebo-controlled trial

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Systemic lupus erythematosus (SLE)

## **Interventions**

1. Intervention group: 3 g LC orally, after meal three times daily for 4 months then withdraw for 2 months to observe the effects
2. Control group: 3 g placebo orally with the same frequency and duration

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Chinese formula LC

## **Primary outcome(s)**

1. Lupus disease activity, measured using SLEDAI-2K score at screening visit and on days 1, 112 and 168
2. Antioxidant function, measured using total antioxidant capacity, nitric oxide (NO), malondialdehyde (MDA), etc, on days 1, 28, 56, 84 and 112
3. Immunological function, measured using antinuclear antibodies (ANA), anti-double strand

deoxyribonucleic acid (DNA), anticardiolipin immunoglobulin G (IgG), immunoglobulin M (IgM), erythrocyte sedimentation rate (ESR), etc, on days 1, 112 and 168

### **Key secondary outcome(s)**

1. Quality of life, measured using the 36-item short-form health survey (SF-36) on days 1, 112 and 168
2. Dosage of oral glucocorticoid, each prescription converted to daily measure of a prednisone-equivalent dose (in milligrams), measured at screening visit and on days 1, 28, 56, 84, 112 and 168
3. Cell markers, measured using cluster of differentiation 31 (CD31), CD34, CD45, CD133, vascular endothelial growth factor receptor 2 (VEGFR2), on days 1, 28, 56, 84 and 112

### **Safety evaluation:**

1. LC medication record, measured on days 1, 28, 56, 84
2. Adverse event record, measured on days 28, 56, 84 and 112
3. Physical examination, measured on days 1, 28, 56, 84 and 112
4. Laboratory tests (complete blood count [CBC], creatinine [Cr], blood urea nitrogen [BUN], AST, ALT), measured at screening visit and on days 1, 28, 56, 84, 112 and 168

### **Completion date**

31/10/2010

## **Eligibility**

### **Key inclusion criteria**

1. Patients fulfill the revised American College of Rheumatology (ACR) criteria for systemic lupus erythematosus (SLE)
2. Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score more than or equal to 2 and less than or equal to 36
3. Daily dose of prednisolone less than or equal to 0.6 mg/kg
4. Age more than or equal to 7 years old and body weight more than or equal to 40 kg, either sex

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Key exclusion criteria**

1. Alcoholism
2. Diabetes mellitus
3. Life-threatening disease
4. Pregnant or nursing women

5. Creatinine clearance less than or equal to 25 cc/min

6. Aspartate aminotransferase (AST), alanine aminotransferase (ALT) more than or equal to 2 x normal limit

**Date of first enrolment**

01/11/2007

**Date of final enrolment**

31/10/2010

## Locations

**Countries of recruitment**

Taiwan

**Study participating centre**

No.123, Dinghu Road

Taoyuan

Taiwan

33375

## Sponsor information

**Organisation**

Department of Health (Taiwan) - Executive Yuan

**ROR**

<https://ror.org/0225asj53>

## Funder(s)

**Funder type**

Government

**Funder Name**

Department of Health (Taiwan) - Executive Yuan

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 05/02/2016   |            | Yes            | No              |