

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

Submission date 18/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/01/2017	Condition category 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

RDCSLs

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

Study design

Double-blind randomised placebo-controlled trial

Primary study design

Interventional

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?
Results article	results	05/02/2016		Yes	No