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

Submission date	Recruitment status	[ ] Prospectively registered
18/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2017	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Heng-Hong Chang

Contact details
No.123, Dinghu Road
Guishan Shiang
Taoyuan
Taiwan
33375
+886 3 319 6200 ext. 2677
tcmchh@adm.cgmh.org.tw

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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. Please note only available in Chinese.

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 measure
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 immunogobulin G (IgG), immunoglobulin M (IgM), erythrocyte sedimentation rate (ESR), etc, on days 1, 112 and 168

Secondary outcome measures
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

Overall study start date
01/11/2007

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

Age group
Mixed

Sex
Both

Target number of participants
90

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

Sponsor details
No.100, Aiguo E. Road
Jhongjheng District
Taipei
Taiwan
10092

Sponsor type
Government

Website
http://www.doh.gov.tw/EN2006/index_EN.aspx

ROR
https://ror.org/0225asj53

Funder(s)

Funder type
Government

Funder Name
Department of Health (Taiwan) - Executive Yuan

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/02/2016		Yes	No