

Application of Dan-Chi-Liu-Wei combination in systemic lupus erythematosus patients to taper steroid use and to prevent disease flare

Submission date 05/01/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 09/02/2007	Overall study status Completed	☐ Protocol
Last Edited 09/05/2019	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

CCMP95-TP-025

Study information

Scientific Title

Application of Dan-Chi-Liu-Wei combination in systemic lupus erythematosus patients to taper steroid use and to prevent disease flare

Study objectives

We hypothesise that Dan-Chi-Liu-Wei (DCLW) Chinese herbal combination would provide a novel complimentary therapy in assisting the tapering of steroid (by approximately 10 mg/day) and decreasing the frequency of disease flare in Systemic Lupus Erythematosus (SLE) patients (by more than 50%) after six months of therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Chang Gung Memorial Hospital: CGMH 95-0951B (9 Nov 2006) and Kaohsiung Medical University Hospital: KMHCTC-950003 (17 Oct 2006).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic Lupus Erythematosus

Interventions

Use of Dan-Chi-Liu-Wei (DCLW) Chinese herbal combination (full strength) versus control (receive a 10% placebo).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dan-Chi-Liu-Wei Chinese herbal combination

Primary outcome(s)

Dosage of steroids after six months of combined therapy (DCLW and regular drugs)

Key secondary outcome(s)

1. Frequency of disease flares after six months of combined therapy (DCLW and regular drugs)
2. Immunologic index (C3, C4, anti-ds-DeoxyriboNucleic Acid [DNA]) after six months of combined therapy (DCLW and regular drugs)

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Using the 1997 revised criteria for the classification of SLE over four categories: patients with mild to moderate activity (Systemic Lupus Erythematosus Disease Activity Index [SLEDAI] grade two to 12) will be recruited
2. Prednisolone use below 20 mg/day

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

53

Key exclusion criteria

1. Currently pregnant, or plan to be pregnant (subjects who become pregnant during study at any time will be excluded)
2. Less than or equal to 18 years of age
3. More than or equal to 60 years of age
4. Serum creatinine more than or equal to 1.4 mg/dl

Date of first enrolment

01/02/2007

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital
Kaohsiung Hsien
Taiwan
833

Sponsor information

Organisation

Department of Health (Taiwan)

ROR

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

Funder(s)

Funder type

Government

Funder Name

Department of Health (Taiwan) (ref:CCMP95-TP-025)

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	01/07/2011	09/05/2019	Yes	No