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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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: KMUHCTC-950003 (17 Oct 2006).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/02/2007

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

Age group
Adult

Sex
Both

Target number of participants
160

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)

Sponsor details
The Committee on Chinese Medicine and Pharmacy
Executive Yuan
-
Taiwan
-
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webmaster@ccmp.gov.tw

Sponsor type
Government

Website
http://www.ccmp.gov.tw/en/index.asp

ROR
https://ror.org/0225asj53

Funder(s)

Funder type
Government

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

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