# 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 [ ] Statistical analysis plan Registration date Overall study status 09/02/2007 Completed [X] Results [ ] Individual participant data Last Edited Condition category 09/05/2019 Musculoskeletal Diseases

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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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: KMUHCTC-950003 (17 Oct 2006).

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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 steriods 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