

A clinical study of Hwangryunhaedoktang in adult atopic dermatitis

Submission date
12/07/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
29/07/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/01/2012

Condition category
Skin and Connective Tissue Diseases

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Namkwen Kim

Contact details
Wonkwang University Oriental Medical Center
1126-1 Sanbon-dong
Gunpo
Korea, South
435-040
drkim@wonkwang.ac.kr

Additional identifiers

Protocol serial number
B090016-1012-0000100

Study information

Scientific Title
A clinical study of Hwangryunhaedoktang in adult atopic dermatitis : a randomised, double-blind, placebo-controlled, multicentre trial

Study objectives

This study is aimed at proving the efficacy, safety and economic evaluation of Hwangryunhaedoktang, with a view to extend the insurance coverage for adult atopic dermatitis patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Wonkwang University Oriental Medical Centre Ethics Committee approved on the 3rd May 2010
2. Sangji University Oriental Medical Centre Ethics Committee approved on the 18th May 2010
3. Wonkwang University Medical Centre Ethics Committee approved on the 18th June 2010

Primary study design

Interventional

Study design

Randomised phase III double blind two arm placebo controlled multicentre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atopic dermatitis - adult type

Interventions

This is a randomised, double-blind, placebo-controlled, multi-centre trial study. Participants will receive hwangryunhaedoktang or a placebo-drug for 8 weeks. Oral administration occurs according to the following statements:

1. Patients in group 1 receive hwangryunhaedoktang and instructions on how to make a tea; they take a packet of the medicine (5.00g) with tepid water for three times a day after meal
2. Patients in group 2 receive the placebo medicine (powdered extract) used in the same way as with group 1

The total duration of all arms is 11 weeks. Timepoints are as follows:

Visit 1: screening

Visit 2: treatment initiation, participants will receive hwangryunhaedoktang or a placebo-drug for 8 weeks.

Visit 3: 2 weeks later of first medication, follow-up

Visit 4: 4 weeks later of first medication, follow-up

Visit 5: 8 weeks later of first medication, follow-up and treatment finish

Post-treatment follow-up will be performed 2 weeks post-intervention. (by phone-call)

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

1. Efficacy:

SCORing Atopic Dermatitis index (SCORAD): the purpose of this questionnaire is to identify the lesional, symptomatic, subjective severities. Measured at treatment period (treatment initiation, 248 weeks later of first medication)

2. Safety:

2.1. Complete Blood Cell Count (CBC)

2.2. Erythrocyte Sedimentation Rate (ESR)

2.3. Blood chemistry

2.4. Urine analysis

2.5. Chest-PA film

Measured at baseline, 8 weeks after first medication

2.6. Vital signs, measured at baseline, treatment period (treatment initiation, 2, 4, 8 weeks after first medication)

Key secondary outcome(s)

Efficacy:

1. Total IgE

2. Eosinophil count

Measured at treatment initiation, 4 and 8 weeks after first medication

3. EuroQol 5-Dimension (EQ-5D)

4. Health Utilities Index Mark 3 (HUI-3)

5. Dermatology Life Quality Index (DLQI)

Measured at treatment initiation, 8 weeks after first medication

Completion date

30/04/2011

Eligibility

Key inclusion criteria

1. Age greater than 19 years, either sex

2. Typical conditions of intermittent or continuous atopic eczema

2.1. Duration of more than 6 months

2.2. Satisfied Hanifin and Rajkas criteria for atopic dermatitis

3. Diagnosed with adult atopic dermatitis by two different oriental medicine doctors

4. Written and informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Other dermatitis or systemic disease except for atopic eczema
2. Administration of steroids and immunosuppressant per os (by mouth) within one week from the interview (topical application not relevant)
3. Women who are pregnant, lactating or without contraception
4. Clinical severe hepatic disease or abnormal liver function tests at least twice the upper limit of normal
5. Other clinical trial within the last 1 month
6. Hypersensitivity or allergy of drugs
7. Disease which can affect the absorption of drugs or disordered digestion after surgery related to the disease
8. Cannot understand written consent or follow this study:
 - 8.1. Mental retardation
 - 8.2. Mental or emotional problems
9. Judged by expert as inappropriate to participate in this study

Date of first enrolment

21/06/2010

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Korea, South

Study participating centre

Wonkwang University Oriental Medical Center

Gunpo

Korea, South

435-040

Sponsor information

Organisation

Korea Health Industry Development Institute (KHIDI)

ROR

<https://ror.org/00fdzyk40>

Funder(s)

Funder type

Research organisation

Funder Name

Korea Health Industry Development Institute (KHIDI) (South Korea) - The Traditional Korean Medicine Research and Development Project

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	23/08/2011		Yes	No