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A clinical study of Hwangryunhaedoktang in adult atopic dermatitis

Submission date	Recruitment status
12/07/2010	No longer recruiting
Registration date	**Overall study status**
29/07/2010	Completed
Last Edited	**Condition category**
03/01/2012	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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

Study design
Randomised phase III double blind two arm placebo controlled multicentre 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 contact details below to request a patient information sheet

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 measure
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 Cound (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)

Secondary outcome measures
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

Overall study start date
21/06/2010

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

Age group
Adult

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Korea Health Industry Development Institute (KHIDI)

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Sponsor type
Research organisation

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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

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	23/08/2011		Yes	No