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Comparing high altitude treatment with current best care in children with Atopic Dermatitis (AD) and asthma within the atopic syndrome by the Wilhelmina Childrens Hospital, Utrecht-Dutch Asthma Centre, DAVOS

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
22/05/2013

Overall study status
Completed

Last Edited
01/10/2019

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
About 20% of children in western European countries have atopic dermatitis (AD) (eczema), often as part of the atopic syndrome (a tendency to develop allergy). Some children continue to have symptoms despite best treatment. We want to provide new treatment options for these children. We are carrying out a study to compare two different new treatments for children with moderate to severe atopic dermatitis. Our goal is to find the most favourable treatment for children with AD. The study's findings should help to improve the quality of life of children with moderate to severe AD.

Who can participate?
Children between 8 and 18 years of age, with moderate to severe AD and asthma, from the Netherlands, can participate in this study.

What does the study involve?
In this study, two treatments are compared. One is a 6-week treatment at the outpatient clinic of the University Medical Centre, Utrecht in the Netherlands. The other is a 6-week treatment at the Dutch Asthma Centre Davos in Switzerland. The treatment that the participant will receive is decided by a process called randomisation, which is like a coin toss. After the treatment period, participants are followed up immediately after the treatment, 6 weeks and 6 months after the treatment. At these time points, we ask the participant to fill in questionnaires, blood and skin samples are taken and a lung function test is done.

What are the possible benefits and risks of participating?
Possible benefits of participating in the study are treatment for the disease, coping with the

disease in a better way and improved quality of life. Long-term benefits are that new treatment will become available for all children with moderate to severe AD. There are no direct risks of participating in this study.

Where is the study run from?
The trial has been set up by the University Medical Centre, Utrecht, Netherlands in collaboration with the Dutch Asthma Centre Davos, Switzerland.

When is the study starting and how long is it expected to run for?
The study started in September 2010 and is expected to run until the summer of 2014.

Who is funding the study?
The University Medical Center Utrecht, MEREM, Vrienden van het WKZ, the European Allergy Clinic Davos and Vereniging Nederland Davos.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A pragmatic randomized controlled trial comparing high altitude treatment with current best care in children with moderate to severe atopic dermatitis (and asthma) in the Netherlands: multidisciplinary treatment at the high altitude clinic Dutch Asthma Centre Davos, Switzerland versus the Wilhelmina Childrens Hospital Utrecht, the Netherlands

Acronym
DAVOS

Study objectives
Multidisciplinary treatment for 6 weeks at the Dutch Asthma Centre Davos will improve disease coping and acceptance and quality of life of children with AD more than multidisciplinary treatment in the Wilhelmina Childrens Hospital. The null hypothesis we test is that there is no difference between the effects of both treatments.

On 03/12/2013 the following changes were made to the trial record:
1. The scientific title was changed from 'A randomised controlled trial comparing high altitude treatment with current best care in children with atopic dermatitis and asthma within the atopic syndrome in the Netherlands. Multidisciplinary treatment at the high altitude clinic Dutch Asthma Centre Davos, Switzerland versus the Wilhelmina Childrens Hospital Utrecht, the Netherlands: a national study' to 'A pragmatic randomized controlled trial comparing high altitude treatment with current best care in children with moderate to severe atopic dermatitis (and asthma) in the Netherlands: multidisciplinary treatment at the high altitude clinic Dutch Asthma Centre Davos, Switzerland versus the Wilhelmina Childrens Hospital Utrecht, the Netherlands'.
2. The anticipated end date was changed from 01/02/2015 to 01/06/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, Utrecht Medical Center, Utrecht, the Netherlands,18/12/2009, Ref: MEC 09-192-K

Study design
Pragmatic randomised controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atopic dermatitis and asthma within the atopic syndrome

Interventions
Intervention: multidisciplinary treatment at the Dutch Asthma Centre in Davos, Switzerland for 6 weeks
Active control: multidisciplinary treatment at the outpatient clinic of the pediatric dermatology and allergology department at the Wilhelmina Childrens Hospital, the Netherlands for 6 weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 03/12/2013:
1. Disease coping and acceptance, measured with the COPEKI/JUCCKI questionnaire
2. Disease-specific quality of life, measured with Children's Dermatology Life Quality Index (CDQLI)
3. Self Administered Eczema Area and Severity Index (SA-EASI)
All measured before the intervention, directly after the intervention, 6 weeks after the intervention and 6 months after the intervention

Previous primary outcome measures:
1. Disease coping and acceptance, measured with the COPEKI/JUCCKI questionnaire directly after the intervention and 6 months after the intervention
2. Disease-specific quality of life, measured with Children's Dermatology Life Quality Index (CDQLI) directly after the intervention, 6 weeks after the intervention and 6 months after the intervention

Secondary outcome measures
Current secondary outcome measures as of 03/12/2013:
1. Disease activity and disease control (for AD and asthma), measured with
1.1. Used (topical) corticosteroids
1.2. Paediatric Asthma Quality of Life Questionnaire (PAQLQ)
1.3. Asthma Control Questionnaire (ACQ)
1.4. Lung function test (spirometry)
1.5. Fractional exhaled Nitric Oxide (FeNO)
1.6. Used asthma medication
All measured before, directly after the intervention, 6 weeks and 6 months after the intervention
1.7. Bronchial hyperresponsiveness (metacholine provocation test)
Measured before intervention and 6 months after intervention
2. Inflammatory and immunological profile, measured with serum levels of Thymus and Activation and Regulated Chemokine (TARC), cytokine profile (Th1/Th2) and eosinophil levels.
Measured before, directly after intervention, 6 weeks and 6 months after the intervention
3. Social and emotional wellbeing of the child and quality of life of the parents, including parental stress and fear.

Measured before, directly after intervention, 6 weeks and 6 months after the intervention
4. Other:
4.1. Bacterial colonization of the skin and nose, protease activity in skin
Measured before the intervention, directly after the intervention, 6 weeks and 6 months after the intervention
4.2. Physical condition (maximal cycle ergometer test) before intervention and 6 months after the intervention
4.3. Extra appointments with the dermatologist/e-consultations/visits to the hospital are recorded during the follow-up period

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1. Disease activity and disease control (for AD and asthma), measured with
1.1. Self Administered Eczema Area and Severity Index (SAEASI)
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All measured before, directly after the intervention, 6 weeks and 6 months after the intervention
1.8. Bronchial hyperresponsiveness (metacholine provocation test)
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Overall study start date
01/09/2010

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Moderate to severe atopic dermatitis
2. 8-18 years
3. Be able to speak and write in Dutch
4. Internet access and be able to use the Digital Eczema Center Utrecht
5. Willing to stay for 6 weeks in the Dutch Asthma Centre Davos

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Current participation in another study

Date of first enrolment
01/09/2010

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 85090
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Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (Netherlands)

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Utrecht (UMCU), Department of (Pediatric) Dermatology and Allergology, MEREM, Vrienden van het WKZ, European Allergy Clinic Davos (EACD), Vereniging Nederland-Davos (VND)

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?
Protocol article	protocol	26/03/2014		Yes	No
Results article	results	01/02/2018	31/01/2019	Yes	No
Results article	results	01/06/2018	01/10/2019	Yes	No