Top care for children with atopic dermatitis (and asthma) within the atopy syndroom, using the digital Eczema Centre WKZ- Dutch Asthma Centre Davos

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The primary research question is:Do children with atopic dermatitis and asthma after a stay in the NAD have a better coping and acceptance of their disease as compared with children treated at the outpatient department of the WKZ?Secondary research...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON40111

Source
ToetsingOnline

Brief title
WKZ-NAD study

Condition

- Bronchial disorders (excl neoplasms)
- Epidermal and dermal conditions

Synonym
asthma, atopic dermatitis, dermatitis

Research involving
Human

Sponsors and support

Primary sponsor: dermatologi'/allergologie
Source(s) of monetary or material Support: Vereniging Nederlands Davos en de European Allergy Clinic Davos.

Intervention

Keyword: asthma, atopic dermatitis, children, e-health

Outcome measures

Primary outcome

Primary outcomes for psychosocial study part are Coping and acceptance of the

disease by the child.

Primary outcome of clinical part of the study is disease activity of atopic

dermatitis.

Secondary outcome

Child: :

- severity of asthma

- self-esteem and feelings of competency

- autonomy (for children of 12 years up)

- anxiety

- asthma -specific quality of life

Parents:

- stress

- anxiety

- disease-specific quality of life

Secundary study parameters that will be investigated in the translational study:

- FeNO (NO in exhaled air)

- Eosinophils

- Total IgE

- Specific IgE to (auto)-allergens

- NO (nitric oxide) in serum

- Profile of Th1 and Th2 cytokines in serum

- OPN (osteopontin) in serum

- TSLP (thymic stromal lymphopoietin) in serum

- TSLP and protease activity in the superficial skin

- Bacterial colonization of the skin

- TSLP DNA polymorphism

Secundary parameters in this second amendement:

- Bacterial colonization of the nose

- Filaggrin mutations

Study description

Background summary

Since 2000, care innovations have been taken place at the department of dermatology and allergology of the Wilhelmina Children's Hospital (WKZ) of the UMC Utrecht. Multidisciplianry care have been developed for children with atopic dermatitis, which is part of the atopy syndrome, and their parents. Last years, we achieved good clinical results in children with atopic dermatitis and asthma who were treated in the Dutch Athma Centre in Davos, Switzerland. Carrying out this reserach proposal, we will support the clinical findings with research evidence. The Digital Eczema Centre Utrecht will be used to optimalize the collaboration between the WKZ and the NAD.

Study objective

The primary research question is:
Do children with atopic dermatitis and asthma after a stay in the NAD have a better coping and acceptance of their disease as compared with children treated at the outpatient department of the WKZ?
Secondary research questions:
Have children with atopic dermatitis and asthma after a stay in the NAD as compared with children treated at the outpatient department of the WKZ :
- less severe and extended eczema
- less severe asthma
- better self-esteem and feelings of competency
- more autonomy (for children of 12 years up)
- less anxiety
- higher asthma -specific quality of life

Have parents of children with atopic dermatitis and asthma after a stay in the NAD as compared with parents of children treated at the outpatient department of the WKZ
- less stress
- less anxiety
- a higher disease-specific quality of life

Secundary research questions that will be investigated in the translational study:

Are there specific immunological markers in children with severe atopic dermatitis and asthma that may predict the (long term) effect of a stay at the NAD?
a. Is the response to treatment at the NAD associated with changes in the level of FeNO and NO?
b. Is the response to treatment at the NAD associated with changes in the level of expressed cytokines (OPN, TSLP and Th1/Th2 cytokines)?
c. Is the activity of atopic dermatitis associated with the level and diversity of specific IgE to (auto)allergens?
d. Is the activity of atopic dermatitis associated with a differential bacterial colonization of the skin and the nose?
e. Is the severity of eczema associated with the amount of TSLP and with protease activity in the superficial skin?
f. Is the severity of eczema associated with an increased frequency of the TSLP polymorphism SNP rs3806933 (-847C>T) as compared to healthy controls?

Secundary research questions that will be investigated in this second amendment:

g. Is there a relation between the severity of atopic dermatitis and bacterial colonization of skin versus nose?
h. Is the severity of atopic dermatitis related to filaggrin mutations?

i. Are filaggrin mutations related to protease activity and/or bacterial colonization of the skin?
j. Are filaggrin mutations related to TSLP polymorphism?
k. Are the translational research parameters related to the parameters from the medical and psychological records?

Study design

Randomized controlled design, randomization after the initial multidisciplinary treatment in the WKZ; Intervention group: stay in the NAD, control group: intensive multidisciplinary treatment at the outpatient department of the dermatology and allergology WKZ.

Intervention

Before the start of the study:
All children will be treated by a dermatologist and a dermatology nurse in two or three consultations in the WKZ/UMC Utrecht. Besides: all children have access to the Digital Eczema Centre Utrecht for e-consult, monitoring and online information focussed on adequate self-management. After that an evaluation will take place, directed on physical and psychosocial complaints. Children who fulfill the inclusion critera will be informed about the study by a member of the multidisciplinary team, using oral and written information.
The intervention:
After signing the informend consent, the child will be discussed in the digital multidisciplinary meeting of the WKZ and NAD teams. A treamtent plan will be noted.
After that, randomization will take place for the intervention group: hospitalization in the NAD or control group: treatment in out-patient clinic of the WKZ.

In both, the NAD and WKZ, the child will be treated by a multidisciplinary team, focussed on adequate self management. The care programme in both hospitals consists of medical treatment, information and training focussed on coping with eczema and asthma, recognizing symptoms, coping with constraints and using possibilities in daily life. All children and their parents can use the Digital Eczema Centre Utrecht during their stay in the NAD or treatment in the WKZ.

I: treatment in the WKZ: Children will be treated for 6 weeks by a multidisciplinary team at the outpatient department of
the WKZ. The child stays at home and exercise all skills in his own, familiar environment.
II: stay in the NAD: Children will stay for 6 weeks in the NAD and lives temporarily separate from his parents. School also takes place in the NAD. The child exercise his skills in a new environment (also psycho-social). The NAD is

a high mountain hospital at 1600 metres above sea level with a less load of airborne-allergens, infectious agents and environmental pollutants.

All children will be discussed during regulary digital meetings by teams of the WKZ and NAD.
After six weeks, treatment will be continued at the dermatology outpatient department of the WKZ.

Study burden and risks

The burden of the study consist of a face-to-face inclusion consultation of thirty minutes. Questionnaires can be filled in in sixty minutes, five times during the study. There are no risks associated with participation.

TARC will be determined as indicator of the severity of the eczema. This will be combined with the usual VP, which is necessary for the diagnosis of allergens. Pain during the VP will be minimilezed using analgetic patches.

The severity of asthma will be determined using a lung-function examination. This examination will be carried out during usual control moments with the pediatrician in the WKZ or NAD.

For the translational part that is added to this study, an extra VP and lung function test is planned 6 weeks after treatment in the WKZ or NAD, to determine the short-term effect of the treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- severe atopic dermatitis (atopy syndrome); children who still need intensive multidisciplinary care after fulfilling the usual 2 or 3 consultations with the dermatologist and dermatology nurse
- 8-18 years
- able to speak and write in Dutch
- internet access and able to use the digital eczema centre Utrecht
-willingness for a stay of 6 weeks in the Dutch Asthma Centre Davos

Exclusion criteria

- Participation in study 08-368; However, children and their parents can be asked to participate in this study after finishing study 08-368

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2010
Enrollment:	258
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-03-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Current Controlled Trials ISRCTN88136485
CCMO	NL27480.041.09