Treatment of hay fever in relation to asthma, in children.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26975

Source
Nationaal Trial Register

Brief title
HATSJOE

Health condition

Allergic Rhinitis (allergische rinitis)
Asthma (astma)

Sponsors and support

Primary sponsor: Erasmuc MC, Rotterdam
Source(s) of monetary or material Support: Astma Fonds

Intervention

Outcome measures

Primary outcome

Percentage of (nose and eye) symptom free days during 3 months in the tree/grass pollen season.

Secondary outcome

1. Allergy symptom score;

2. (Rescue)medication free days;

3. AR-specific quality of life;

4. Patient’s preference of medication.

Outcomes regarding the effectiveness of AR-treatment on asthma: % days without asthma symptoms, asthma symptom score, asthma medication free days, asthma quality of life, and degree of asthma control.

Study description

Background summary

Therapeutic intervention for mild or intermittent AR includes antihistamines or intranasal corticosteroids (INCS). Both types of drug have certain benefits and it is unclear which of the two are more effective and preferred by younger patients (children aged 6 to 18 years old). Besides, the patients tend to use INCS when they have complaints instead of continuously during the hay fever season, as prescribed by the GP. This could also influence the effectiveness of INCS.
Allergic rhinitis (AR) and asthma are considered manifestations of the same origin affecting different parts of the respiratory tract. It has been suggested that adequate treatment of AR might be beneficial for the lower airways. Whereas INCS and perhaps antihistamines may be a promising additive treatment to reduce asthma symptoms in patients with rhinitis and mild asthma, more research is needed.
In this randomized controlled singleblind trail we will select children (6-18 years old) with seasonal AR (hay fever) under treatment by the general practitioner. During the hay fever season children will get either antihistamines on demand, INCS on demand or INCS continuously. We will compare the percentage of (nose and eye) symptom free days during the pollen season and the effect of treatment on asthma symptoms and control.

Study objective

NA

Study design

Patients have to fill in an online diary on a daily basis for 3 months. During these 3 months several questionnaires will be conducted. The measure points will be at the start, halfway (6 weeks) and at the end of the study.

Intervention

Children will receive medication for a period of 3 months during the hay fever season. This medication can be taken in three different schedules:

1. Levocetrizine, 5mg, if necessary;

2. Fluticason, 50mcg, 1 or 2 sprays a day in each nostril, when necessary;

3. Fluticason, 50mcg, 1 or 2 sprays in each nostril, daily.

Contacts

Public
Afdeling huisartsgeneeskunde Erasmus MC
Intern adres: GK 1048
Postbus 2040
J.B. Wartna
Burg. S'Jacobplein 51
3051 CA
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7043550
Scientific
Afdeling huisartsgeneeskunde Erasmus MC
Intern adres: GK 1048
Postbus 2040
J.B. Wartna
Burg. S'Jacobplein 51
3051 CA
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7043550

Eligibility criteria

Inclusion criteria

1. Children aged 6-18 years;

2. Recruitment in general practice based on doctor's diagnosis AR (ICPC R97) or prescription

of allergy medication (antihistamines, INCS) in the past;

3. Sensitization to grass and/or tree pollen (determined by CAP-RAST, class >= 2);

4. Present symptoms of allergic rhinitis and conjunctivitis. Severity will be determined by a retrospective symptom score (patients have to recall their complaints during the previous hay fever season). Seven complaints of nose (sneezing, nose blockage, runny nose, itching nose) and eye (itching eyes, redness and tearing eyes), will be determined. Each symptom is recorded on a scale from 0 to 3. A minimum of 7 out of the maximum of 21 points is required to be included in the study.

Exclusion criteria

1. Use of INCS one month prior to randomization or antihistamines one week prior to randomization;

2. Currently pregnant or breastfeeding;

3. Spending a significant amount of time abroad during the study period;

4. Not be able to speak and understand the Dutch language sufficiently for both parents as the patients.
5. Not having internet access to fill in the diary and questionnaires

6. Contraindication determined by GP (problematic family situation, psychological problems or
contra-indication for the medication)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2012
Enrollment:	477
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-05-2012
Application type:	First submission

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
NTR-new	NL3276
NTR-old	NTR3429
Other	Astma Fonds : 3.4.11.049
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A