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

Gepubliceerd: 11-05-2012 Laatst bijgewerkt: 18-08-2022

NA

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26975

Bron
Nationaal Trial Register

Verkorte titel
HATSJOE

Aandoening

Allergic Rhinitis (allergische rinitis)
Asthma (astma)

Ondersteuning

Primaire sponsor: Erasmuc MC, Rotterdam
Overige ondersteuning: Astma Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

NA

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	477
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3276
NTR-old	NTR3429
Ander register	Astma Fonds : 3.4.11.049
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A