Effects of treated and untreated Allergic Rhinitis on Mood, Cognitive functions and Actual Driving Performance

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON34316

Source
ToetsingOnline

Brief title
Rhinitis and Driving

Condition

- Allergic conditions

Synonym
Allergic Rhinitis; Hay-fever

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Een "Unrestricted Grant" van GSK Nederland,GlaxoSmithKline

Intervention

Keyword: Allergic Rhinitis, Cognition, Driving, Mood

Outcome measures

Primary outcome

The following outcome variable will be used to evaluate the primary objectives:

Study parameter : Standard Highway Test

Outcome variable: Standard Deviation of Lateral Position (SDLP): cm.

Outcome variable: Standard Deviation of Speed (SDSP): km.

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Study parameter : WLT- 15 verbal Memory test

Outcome variable: Total words recalled (Immediate recall)

Outcome variable: Total words recalled after 30 minutes (delayed recall)

Secondary outcome

An exploratory Health Cost analysis will be performed on treated vs untreated

AR.

Variable: Cost effectiveness analysis

Outcome variable: PRODISQ procedure as described by Koopmanschap et al 2005

Study description

Background summary

Previous research has shown that patients suffering from Allergic Rhinitis (AR) not only suffer from direct symptoms of their condition but also report a

decreased quality of life. More specific this relates not only to psychological wellbeing but also to diminished cognitive functions such as memory and concentration (Kremer et al., 2001). In a recent study of our group we showed that in tasks with a higher and longer lasting cognitive load symptomatic AR patients performed significantly worse compared to controls (Hartgerink-Lutgens et al., 2009).

The finding of a direct relationship between AR symptoms and cognitive functioning strongly suggests implications of AR daily life functioning, safety and workplace productivity. Whereas untreated AR was previously thought only to affect subjective wellbeing it now seems that cognitive functioning might be directly impaired which could lead to potentially dangerous situations in daily life such as driving a car or operating machinery. This would add an argument to re-evaluate treatment protocols that are now mainly aimed at reducing AR symptoms and increased wellbeing.
In this study we will investigate the effect of an allergen challenge in AR patients on actual driving and memory functions. A comparison in performance will be made between untreated patients and patients treated with systemic or topical drugs.

Hartgerink-Lutgens I., Vermeeren A., Vuurman E., Kremer B. Disturbed cognitive functions after nasal provocation in patients with Seasonal Allergic Rhinitis. Clinical and Experimental Allergy. Published online: 18 February 2009.

Kremer, B., et al., Generic or disease-specific quality of life scales to characterize health status in
allergic rhinitis? Allergy, 2001. 56(10): p. 957-63.

Study objective

The primary objective of this study is to evaluate the effects of two types of AR treatment & placebo in counteracting AR*s effects on Cognition and Driving. Therefore, the effects of nasal provocation in AR patients on cognitive functions and actual driving performance after treatment will be determined.

Study design

This will be a single-centre, randomized, double-blind, placebo-controlled 4-way crossover study conducted in twenty AR patients between 21-40 years of age. Participants who qualify will enter the study and be tested on 4 different occasions outside the pollen season. Participants will be randomized to one of four computer generated sequences and the actual provocation phase will be conducted using a cross over design. There will be four test conditions, and all participantss will participate in all four conditions. Treatments are a systemic treatment (cetirizine 10mg), a topical treatment (fluticasonfuroaat)

and placebo. Nasal challenge consists of either vivodiagnost® allergen or placebo.
There will be at least a 14 day washout between treatments. This will lead to 4 conditions for patients:

1. Placebo Nasal challenge + placebo treatment
2. Nasal challenge + placebo treatment
3. Nasal challenge + systemic treatment
4. Nasal challenge + topical treatment

Each treatment phase will consist of one day of testing + treatment plus a 5-day period immediately preceding each test day in which only topical treatment will be administered. The schedules and procedures will be identical for all four periods(conditions) of the study. All patients will be collected from their homes by a study assistant and transported to the Institute. After testing is concluded at the end of the test day they will also be returned to their homes.

On each test day subjects will first fill out a few questionnaires. Then a nasal provocation will be administered to elicit an allergic reaction and subjects will receive a dose of active drug or placebo. After two hours subjects will perform a standard Highway driving test lasting 60 minutes during which a memory test is administered. After conclusion of the driving test the subject fill out a second set of questionnaires and are dismissed.

Intervention

All subjects will go through the following for conditions with treatments:

Condition 1. Placebo Nasal challenge + placebo treatment
Condition 2. Nasal challenge + placebo treatment
Condition 3. Nasal challenge + systemic treatment (Cetirizine 10mg)
Condition 4. Nasal challenge + topical treatment (Fluticasonfuroaat 27,5 microgram)

Study burden and risks

The burden on participants is limited. Time investment is limited to 4 full mornings and a test session of about 3 hours. No exceptional mental or physical strain is imposed on participants. The procedures of the driving test have been proven to be safe in over 70 projects completed with the procedure previously. The provocation procedure is administered routinely in diagnosis of SAR. Finally, the drugs used have been on the market for over two years and have no known or expected serious side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1 Participants must be normal healthy males or females, age between 21 and 45 years, diagnosed with seasonal AR (SAR), also known as Intermittent Rhinitis (ITR) Anti-allergic treatment during the previous season, positive radioallergosorbent test for serum-specific immunoglobulin E or positive skin prick test for tree/ and/or grass- and/or weed pollen.
2. Participants must be experienced drivers. That is, each shall have held a driver*s license for at least the preceding two years and shall have driven more than 5,000 km/yr (3,000 miles/yr) during that period.
3.Participants must be in general good health as confirmed by routine clinical and laboratory testing.
4 Participants must be able and willing to give Informed consent

Exclusion criteria

1. Participants who have clinically significant abnormal physical findings or vital signs at the Screening physical examination (as determined by the Investigator) which could interfere with the objectives of the study. This includes participants who have any history or symptoms of chronic illness including asthma, history of psychotic disorders, drug addiction or abuse of drugs or alcohol which could interfere with the completion of the study.
2.Participants requiring any CNS medication during the study, or medication with sedative effects which could interfere with the objectives of the study.
3.Participants who have taken participated in an investigational drug trial within one month prior to the Screening Visit.
4. Participants with a history of allergies to more than two classes of medication or who are allergic to or cannot tolerate antihistamines.
5. Excessive smoking; i.e., more than ten cigarettes per day or the equivalent.
6. Excessive consumption of beverages containing caffeine; i.e., more than five cups per day.
7. Participants with active seasonal and/ or perennial allergic rhinitis.
8. Pregnant or nursing females.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2011
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	ceterizinedihydrochloride
Generic name:	ceterizinedihydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-09-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2010-021933-30-NL
ClinicalTrials.gov	nct01239264
CCMO	NL33269.068.10