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Morning versus evening dosing of desloratadine in seasonal allergic rhinitis: a randomised controlled study

Submission date 31/01/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2005	**Overall study status** Completed	
Last Edited 18/02/2008	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Rolf Haye

Contact details
Dept. of Otolaryngology
Rikshospitalet
Oslo
Norway
0027

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P02278

Study information

Scientific Title

Study objectives
The aim of this study was to examine the efficacy of the antihistamine desloratadine at different time points during the day and to evaluate whether the time of dosing of desloratadine has any impact on the treatment efficacy in seasonal allergic rhinitis (SAR).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol and the patient informed consent form were approved by Ethics Committees and Health Authorities in each of the participating countries.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Seasonal allergic rhinitis

Interventions
Patients were randomised into one of two treatment groups with dosing of 5 mg desloratadine tablets either in the morning between 07 - 09 (AM-group) or evening between 19 - 21 (PM-group) in a 1:1 ratio.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Desloratadine

Primary outcome measure
The mean change from baseline for the AM last hour total symptom score (TSS) over the 2 weeks treatment period.

Secondary outcome measures
1. Interference with sleep and interference with daily activity
2. The number of hours spent outdoors

Overall study start date
11/04/2001

Completion date
02/09/2002

Eligibility

Key inclusion criteria
1. Patients 18 years or above with a minimum of two years history of SAR confirmed by either a positive skin prick test or a positive serologic allergen test to the relevant seasonal allergen
2. Clinically symptomatic with SAR at baseline/inclusion with a minimum total nasal symptom score (rhinorrhoea, congestion, itching and sneezing) of at least 6 and rhinorrhoea being minimum 2 (moderate)
3. Willingness to adhere to dosing and visit schedule
4. Females of childbearing potential have to use medically accepted methods of birth control
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
663

Key exclusion criteria
1. Pulmonary disease, perennial rhinitis, sinusitis, rhinitis medicamentosa, pollen desensitisation during the last 6 months
2. Respiratory tract infection within the last two weeks
3. Structural nasal abnormalities (including polyps)
4. Use of oral, nasal, ocular decongestants, corticosteroids in any form (except mild dermatological group I corticosteroids allowed in only small areas), other antihistamines (oral or topical), any investigational drug during the last 30 days
5. Pregnant or nursing females

Date of first enrolment
11/04/2001

Date of final enrolment
02/09/2002

Locations

Countries of recruitment
Denmark

Finland

Iceland

Norway

Sweden

Study participating centre
Dept. of Otolaryngology
Oslo
Norway
0027

Sponsor information

Organisation
Schering-Plough AS (Norway)

Sponsor details
Ankerv. 209
Eiksmarka
Norway
1359

Sponsor type
Industry

ROR
https://ror.org/0118bra88

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough in the Nordic countries

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?
Results article	Results	02/02/2005		Yes	No