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Use of nasal spray for common cold treatment

Submission date
02/05/2012

Recruitment status
No longer recruiting

Registration date
08/05/2012

Overall study status
Completed

Last Edited
14/11/2013

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Upper respiratory tract infection (common cold) is one of most widespread diseases worldwide; however, no effective therapy for this condition has been developed so far.
The aim of this study was to test the hypothesis that treatment with nasal spray containing carrageenan was superior to placebo (saline solution) nasal spray in adult patients with common cold

Who can participate?
Patients could participate if they were of age of 18 years and more and had had early symptoms of common cold

What does the study involve?
All participants received either nasal spray containing carrageenan or saline solution nasal spray which was to be used 3 times daily during one week. During the study period, all patients kept a diary recording either intensity of 8 symptoms (headache, muscle ache, chilliness, sore throat, blocked nose, runny nose, cough and sneezing) using a 4-point scale or answering a question whether they had any symptoms of common cold. Additionally, at Visits 1 (day 1), 2 (days 3-4) and 3 (days 10-11) nasal fluid was collected. After study end duration of disease, intensity of symptoms over time and viral load in nasal fluid was compared in groups receiving carrageenan spray treatment and placebo.

What are the possible benefits and risks of participating?
There was no immediate benefit for study participants; however, there was possible future benefit for society resulting from development new safe and effective therapy for common cold. Due to the nature of the condition under study, no significant risks were anticipated.

Where is the study run from?
General Hospital of Vienna

When is study starting and how long is it expected to run for?
The study ran from 4th January, 2010 (first patient enrolled) until 15 June 2011.

Who is funding the study?
Marinomed Biotechnologie GmbH, Vienna, Austria

Who is the main contact?
Marinomed Biotechnologie GmbH
office@marinomed.com

Contact information

Type(s)
Scientific

Contact name
Prof Christian A Müller

Contact details
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1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Carrageenan nasal spray against common cold

Acronym
CANASCOL

Study objectives
Primary objective:
To evaluate the effect of the nasal spray on the duration of symptom clearance of common cold compared to placebo treatment

Secondary objectives:
1. To evaluate the effect of the nasal spray on the duration of disease of a common cold defined as the time period between first and last day with symptoms (symptom score > 0) followed by 48 hours without symptoms
2. To evaluate the effect of the nasal spray on the severity of symptoms of common cold compared to placebo
3. To evaluate the effect of the nasal spray compared to placebo treatment with respect to

symptom-free days during the observation period of 21 days
4. To evaluate the effect of the nasal spray compared to placebo treatment with respect to the use of co-medication between days 8 - 21 (after finishing the treatment with the carrageenan nasal spray)
5. To evaluate the effect of the nasal spray compared to placebo treatment with respect to the number of newly acquired viral co-infections
6. To investigate the effects of the nasal spray on the presence of biomarkers and common cold viruses in nasal secreted fluid samples

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical University of Vienna General Hospital Ethics Committee, 17 November 2009 ref: 879-2009

Study design
Randomised double-blind two-centre parallel group placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Marinomed Biotechnologie GmbH (office@marinomed.com) to request a patient information sheet

Health condition(s) or problem(s) studied
Early symptoms of common cold

Interventions
Coldamaris Prophylactic gel nasal spray versus matching placebo (saline solution) nasal spray, 3 times a day for 7 day

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Duration of symptom clearance defined as the time period between first and last day with symptoms

Secondary outcome measures
1. The duration of disease being defined as the time period between first and last day with symptoms (symptom score > 0) followed by 48 hours without symptoms
2. Total symptom score (TSS) (Sum of 8 symptoms)
3. Systemic symptom scores on separate study days
4. Local symptom scores on separate study days
5. Individual symptom scores on separate study days
6. Number of days without symptoms during the observation period
7. Consumption of medication (additional to study treatment) during the study period
8. Number of newly acquired viral infections during the observation period
9. Identification of virus, determination of viral titers in nasal secreted fluid
10. Determination of newly acquired or resolved infections
11. Determination of the concentration of cytokines using a Multiplex array
12. Subject acceptability assessments: subjects opinion of the study product / subjects willingness to use the product in the future

Overall study start date
04/01/2010

Completion date
15/06/2011

Eligibility

Key inclusion criteria
Patients eligible for inclusion in this study had to fulfil all of the following criteria:
1. Age ≥18 years
2. Patients have given informed consent, and received a copy of signed consent form prior to any study related procedures
3. Symptoms of URTI (Upper respiratory tract infection), such as rhinitis/nasal obstruction /sneezing or cough or sore throat or otitis
4. Subjects consider that they are in an early stage of a common cold with symptoms of no more than 48 hours duration
5. Subjects have a symptom score of at least 2 and no more than 9 of sum of severity scores on entry to the study. The score is calculated by summing 8 symptom scores (headache, malaise, chill, sore throat, nasal obstruction, nasal discharge, cough, and sneezing) with each item rated 0=absent, 1=mild, 2=moderate, 3=severe.
6. Subjects agree to refrain from taking any products intended to prevent, intervene in, or treat cough/colds/flu, starting at study entry and continuing through Day 7

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
200

Key exclusion criteria
A patient had not to be recruited in this study if at least one single criterion of the subsequent list was fulfilled:
1. No informed consent
2. Known hypersensitivity or allergy to any component of the test product
3. Severe cardiovascular, endocrinological, neurological, respiratory, gastrointestinal disease or a history or any current disease that is considered by the investigator as a reason for exclusion
4. Proven hypersensitivity of allergy resulting in hayfever and rhinitis
5. Severe nasal septal deviation or other non-infectious condition that could cause nasal obstruction
6. A history of any nasal or sinus surgery in the past that in the opinion of the investigator may influence symptom scores
7. Currrent medication other than oral contraception, that is considered by the investigator as a reason for exclusion e.g. systemic steroids or intranasal medication
8. Recent treatment of common cold that in the opinion of the investigator may influence symptom scores
9. An unrelated infection that in the opinion of the investigator may influence the symptom scores (gastrointestinal infection, other viral diseases such as measles, mumps)
10. The subject is related to any study personnel, or has any other close ties or conflicts of interest with the research team or the study sponsor
11. The subject has received any investigational drug or participated in a clinical trial within 4 weeks of entry to this study
12. The subject has a clinically significant disease that could interfere with participation in the study, with the intervention being studied, or with the evaluation of symptoms. Specific exclusions include immune deficiency, autoimmune disease, substantive cardiovascular, endocrinological, neurological, respiratory, or gastrointestinal disease
13. A history of allergic rhinitis with current eye or nose itching or sneezing, chronic obstructive pulmonary disease with current cough were also the exclusions

Date of first enrolment
04/01/2010

Date of final enrolment
15/06/2011

Locations

Countries of recruitment
Austria

Study participating centre

Medical University of Vienna General Hospital
Vienna
Austria
1090

Sponsor information

Organisation
Marinomed Biotechnologie GmbH (Austria)

Sponsor details
Veterinärplatz 1
Vienna
Austria
1210

Sponsor type
Industry

Website
http://www.marinomed.com

ROR
https://ror.org/01cabyw47

Funder(s)

Funder type
Industry

Funder Name
Marinomed Biotechnologie GmbH (Austria)

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	13/11/2013		Yes	No