ISRCTN14067635 https://doi.org/10.1186/ISRCTN14067635

Clinical study to assess the tolerance and efficacy of a nasal spray: Stérimar Stop & Protect Rhume/Cold for relief of symptoms in patients with an upper respiratory tract infection (common cold)

Submission date
04/03/2021

Recruitment status
No longer recruiting

Registration date
18/03/2021

Overall study status
Completed

Last Edited
22/03/2021

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The objective of this clinical study is to assess the effects of Stérimar Stop & Protect Rhume /Cold for relief of symptoms in patients with an upper respiratory tract infection (common cold).

Who can participate?
People aged 18 - 60 years old, with symptoms of the common cold.

What does the study involve?
Participants will be randomly allocated to receive either Sterimar S&P Cold or Blocked Nose They could be used up to 6 times a day, 2 pulverisations into each nostril for 14 days at the maximum.

What are the possible benefits and risks of participating?
None

Where is the study run from?
1. Centro di Farmacologia Clinica per la Sperimentazione dei Farmaci (Italy)
2. Azienda Ospedaliero - Universitaria "Policlinico - Vittorio Emanuele" (Italy)

When is the study starting and how long is it expected to run for?
December 2015 to July 2018

Who is funding the study?
Church and Dwight (France)

Who is the main contact?
Ms Constance Prime, constance.prime@churchdwight.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SSP13081.25

Study information

Scientific Title
Assessment of the tolerance and efficacy of Stérimar Stop & Protect Rhume/Cold - randomized, double-blind, controlled versus Stérimar Hypertonic parallel-group, non-inferiority clinical study

Study objectives
Assessment of the tolerance and efficacy of a nasal spray : Stérimar Stop & Protect Rhume/Cold

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2016, Sezione Comitato Etico Area Vasta Nord Ovest (Via Roma 67, 56126 Pisa, Italy; +39 (0)50996111; no email provided), ref: 176/2017/PO

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Upper respiratory tract infection (common cold)

Interventions
The study groups will comprise patients with symptoms of common cold, satisfying the inclusion and exclusion criteria and agreeing to take part in this randomized, double blind, controlled, parallel group, non-inferiority clinical study.
Patients will be randomized in a 1:1 ratio, in a double blind way, in one of the 2 arms (Sterimar S&P Cold vs Blocked Nose)

The study products were supplied in the form of a 20ml pump delivering doses of 140 µmL, they did not require any specific preparations for use and were provided ready to use. They could be used up to 6 times a day, 2 pulverisations into each nostril for 14 days at the maximum.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sterimar S&P Cold, Sterimar Blocked Nose

Primary outcome(s)
Illness severity measured using Wisconsin Upper Respiratory Symptom Survey (WURSS-21) questionnaire each day.

Key secondary outcome(s)
1. Illness duration measured using Wisconsin Upper Respiratory Symptom Survey (WURSS-21) questionnaire each day until last time answering “Yes” to the question “Do you feel you still have a cold?”
2. Use of rescue medication measured using patient-reported diary each day
3. Patient satisfaction measured using 10-point Likert scale at the final visit of the patient to the center at the end of the study
4. Patient acceptability measured using 10-point Likert scale at the final visit of the patient to the center at the end of the study
5. Patient willingness to use the product in the future measured using 4-point scale at the final visit of the patient to the center at the end of the study
6. Safety measured using means of the assessment of all the adverse or serious adverse events reported during the study recorded to patient diary

Completion date
11/07/2018

Eligibility

Key inclusion criteria

1. Symptoms of common cold
2. Aged from 18 to 60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Patients with symptoms started > 48 hours before enrolment.
2. Patients presenting an oral temperature greater than 38.9°C.
3. Patients with positive results on a streptococcal antigen screening test.
4. Patients with signs of lower respiratory tract disease.
5. Patients with history of allergic (seasonal or perennial) rhinitis or reporting sneezing or itching of the nose or eyes at the time of enrolment.
6. Patients with history of asthma or reporting cough, wheezing or shortness of breath at the time of enrolment.
7. Patients with current or reporting history of recurrent bronchitis, otitis or pharyngitis.
8. Patients with recent or current sinus infection (diagnosed by a physician in the past 30 days) or reporting history of recurrent sinusitis (more than two per years).
9. Patient with immune system disorder (autoimmune and immune deficiency disease such as SLE or AIDS).
10. Patients with a clinical significant cardiovascular, endocrine, neurological, respiratory, or any other current disease considered by the Investigator as an exclusion criterion, e.g. chronic respiratory or lung disease or chronic obstructive pulmonary disease (COPD).
11. Patients with severe nasal septum deviation or other current condition that can cause nasal obstruction, such as nasal polyps or nasal / sinus surgery in the past, able to influence symptoms scores.
12. Pregnant women.
13. Patients using saline nose drops or nasal sprays or pumps other than the study products, antibiotics, antivirals, nasal or systemic steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), intranasal medicines, decongestants, antihistamines, combination cold formulae, Echinacea, supplements containing ≥ 10 mg zinc or ≥ 100 mg vitamin C, i.e. using OTC or prescribed medication (other than for contraception) able to influence symptoms scores at the time of enrolment.
14. Patients with known hypersensitivity or allergy to any component of the study medication or of the rescue medication (acetaminophen).
15. Patients smoking during the past 12 months.
16. Patients with a history of alcohol or drug abuse.
17. Patients participating to any investigational drug trial within 4 weeks before screening.

Date of first enrolment
20/04/2016

Date of final enrolment
23/04/2018

Locations

Countries of recruitment
Italy

Study participating centre
Centro di Farmacologia Clinica per la Sperimentazione dei Farmaci
Pisa
Italy
56126

Study participating centre
Azienda Ospedaliero - Universitaria "Policlinico - Vittorio Emanuele"
Catania
Italy
95123

Sponsor information

Organisation
Church & Dwight (United States)

ROR
https://ror.org/01vaj9161

Funder(s)

Funder type
Industry

Funder Name
Church and Dwight

Alternative Name(s)
Church & Dwight Co., Inc., Church & Dwight Company, Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other