

# 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)

<b>Submission date</b> 04/03/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/03/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

Ms Constance Prime

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### 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

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### **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  $\geq 10$  mg zinc or  $\geq 100$  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