

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/03/2021	Condition category 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

Contact details

Sofibel

110-114 rue Victor Hugo

Levallois-Perret

France

92686

+33 6 16 14 32 05

constance.prime@churchdwight.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/12/2015

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

Age group

Other

Sex

Both

Target number of participants

102

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)

Sponsor details

Sofibel

110-114 rue Victor Hugo

Levallois-Perret

France

92686

+33 (0)1 49 68 41 00

Marita.Alegre@churchdwight.com

Sponsor type

Industry

Website

<http://www.churchdwight.com/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/06/2021

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