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A study to see if treatment with Otrivine (xylometazoline hydrochloride) can improve the quality of life in patients suffering with nasal congestion due to a common cold

Submission date
14/07/2022

Recruitment status
No longer recruiting

Registration date
16/08/2022

Overall study status
Completed

Last Edited
07/08/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
This study is to see if an over-the-counter nasal spray can improve the quality of life for people suffering from a blocked nose with the common cold. The drug being tested is called Otrivine (xylometazoline hydrochloride) which helps to open up and clear the nasal passages by reducing the excessive secretions in the nose and returning swollen blood vessels to their normal size.
A blocked nose with a common cold is one of the most bothersome symptoms of the common cold and has been shown to have a significant impact on the quality of life, work productivity, absence from work, and sleep quality. This study will help to see if Otrivine can help to relieve the symptoms of a blocked nose and whether this can improve the quality of life of those suffering from this illness.

Who can participate?
Adults with nasal congestion that started within 24 hours of starting screening, and at least one other common cold symptom among runny nose, plugged nose, sneezing, sore throat, scratchy throat, cough, hoarseness, head congestion, chest congestion and feeling tired

What does the study involve?
Participants will be informed about the study and give their informed consent to take part. They will then complete a screening questionnaire which will include details about their cold symptoms, medical history and medication use. If confirmed to be eligible, the study drug will be shipped to their home. Participants will take part in the study for approximately 8 days. During that time, they will take Otrivine as per label instructions up to 3 times per day for a maximum of 7 days. They will also complete a questionnaire which will take approximately 5-10 minutes per day.
This study will take place at one virtual site located in the UK and will recruit approximately 125 adults.

What are the possible benefits and risks of participating?
Participants will be provided one bottle of Otrivine Adult Nasal Spray, which is currently available without a prescription in the UK. Otrivine Adult Nasal Spray contains the active ingredient xylometazoline hydrochloride which may help to open up and clear the nasal passages by reducing the excessive nasal secretions and returning the swollen blood vessels to their normal size. While using Otrivine Adult Nasal Spray participants may experience relief from your stuffy nose. Participants will be helping the researchers to identify quality-of-life benefits from this nasal decongestant.
Common side effects which may affect up to 1 in 10 people include headache, nasal dryness, nasal discomfort, nausea and local irritation after using the spray.
Uncommon side effects which may affect up to 1 in 100 people include nosebleeds.
Very rare side effects which may affect up to 1 in 10,000 people include hypersensitivities, such as rash and pruritis (itchiness), disturbance of vision and palpitations, increased heart rate and angioedema.
Other side effects where the incidence is not known to include a burning sensation in the nose and throat.
These risks will be minimised by limiting the administration of Otrivine up to 3 times per day for 7 days as per label instructions. The participant will also be encouraged to report any side effects, discomforts or health issues that they have during the study to the Investigator either through the study app, via phone or email. The study app will also prompt them to record any issues that they have during the study and if any are reported an Investigator will follow up with a phone call to the participant.

Where is the study run from?
The Virtual Clinical Trials Centre (United Kingdom)

When is the study starting and how long is it expected to run for?
July 2022 to December 2022

Who is funding the study?
GlaxoSmithKline (United Kingdom)

Who is the main contact?
Dr Helen Shaw (United Kingdom)
helen.shaw@thevctc.com

Contact information

Type(s)
Public

Contact name
Dr Helen Shaw

Contact details
10 Pear Tree Close
Hartshorne
United Kingdom
DE117AQ
+44 (0)7860 820744
helen.shaw@thevctc.com

Type(s)
Principal investigator

Contact name
Dr Ravikumar Ravindran

Contact details
10 Pear Tree Close
Derbyshire
United Kingdom
DE11 7AQ
+44 (0)7860 820744
ravikumar.ravindran@thevctc.com

Type(s)
Scientific

Contact name
Mrs Mizpah Lamptey

Contact details
Haleon
Mizpah Lamptey
Senior Clinical Study Manager
St Georges Avenue
Weybridge
United Kingdom
KT13 0DE
+44 (0)1932 959530
Mizpah.n.Lamptey@haleon.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT05556148

Integrated Research Application System (IRAS)
1006069

Protocol serial number
218317

Study information

Scientific Title
A real-world evidence study evaluating quality of life parameters following treatment with Otrivine (xylometazoline hydrochloride)

Study objectives

Otrivine (xylometazoline hydrochloride) is an effective and well-tolerated decongestant nasal spray that relieves nasal congestion in common cold sufferers and provides long-lasting relief. The specific goal of this study is to investigate the effect of Otrivine on Quality of Life factors in adults with nasal congestion due to a common cold.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2022, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8070, +44 (0)207 104 8019, +44 (0)2071048089; edgbaston.rec@hra.nhs.uk), ref: 22/WM/0177

Study design
Interventional single-arm open-label study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nasal congestion associated with a common cold

Interventions
The drug being tested is Otrivine Congestion Relief 0.1% Nasal Spray. This is a marketed product available over-the-counter in the UK. Otrivine Congestion Relief 0.1% Nasal Spray, and the nasal solution contains 1 mg/ml of xylometazoline hydrochloride. Each metered-dose spray delivers 0.14 mg of xylometazoline hydrochloride. In this single-arm, open-label study, Otrivine will be used, as per label instructions, by adults aged 18 and over, for the symptomatic relief of nasal congestion associated with the common cold. The frequency of dose will be determined by patients based on their congestion symptoms. Patients may dose one application in each nostril up to 3 times daily as needed, for up to 7 consecutive treatment days. In this study, the non-drug intervention is the completion of quality-of-life (QoL) assessments by patients once every 24 hours. The assessment includes The Wisconsin Upper Respiratory Symptom Survey 21 (WURSS-21). The WURSS-21 is the short version of the Wisconsin Upper Respiratory Symptom Survey, an evaluative illness-specific QoL instrument, designed to assess the negative impact of acute upper respiratory infection, presumed viral (the common cold). The assessment also includes a sponsor-derived product-specific QoL questionnaire. These measures will provide the sponsor with information on the effects of Otrivine over the natural course of their common cold. This will enable the sponsor to evaluate the daily effects that may be attributable to Otrivine.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Otrivine (xylometazoline hydrochloride nasal spray)

Primary outcome(s)
Scores over time on Days 0, 1, 2, 3, 4, 5, 6, 7 in:
1. Wisconsin Upper Respiratory Symptom Survey – 21 (WURSS-21) total score
2. WURSS-21 total symptom domains
3. WURSS-21 total QoL domains
4. Each of the WURSS-21 symptom domains (10 in total)

Key secondary outcome(s))
Post Otrivine use score on Days 1, 2, 3, 4, 5, 6, 7, for each of the following additional health-related QoL factors:
1. Snoring
2. Alertness the morning after
3. Feeling self-conscious about how you sound
4. Smell
5. Taste
6. Feeling self-conscious around people
7. Energy
8. Motivation

Safety outcome measures: to record adverse events (AEs) during the study period, including: Number and percent of patients reporting AEs or serious AEs (SAEs) while on treatment that are
1. Related to product
2. Not related to product

Completion date
20/12/2022

Eligibility

Key inclusion criteria
1. Aged 18 years old and over at the signing of the informed consent
2. Reporting nasal congestion and at least one other common cold symptom among runny nose, plugged nose, sneezing, sore throat, scratchy throat, cough, hoarseness, head congestion, chest congestion and feeling tired
3. Reporting a minimum score of 5 (moderate) for plugged nose associated with common cold symptoms and at least one other symptom of the common cold (at least mild score of 3) as per the WURSS-21 questionnaire at screening and within 24 hours of study product receipt
4. Initiation of cold symptoms within 24 hours of initiation of screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
136

Key exclusion criteria
1. Allergic to xylometazoline hydrochloride or any of the other ingredients in the spray
2. Individuals who have had recent neurosurgery or self-report narrow-angle glaucoma, chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis), an enlarged prostate gland, a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (pheochromocytoma)
3. Taking monoamine oxidase inhibitors (MAOIs) or have stopped taking them in the last 14 days
4. Individuals who are pregnant, lactating, or plan to be pregnant or lactating during the course of the study
5. Is currently using or has used a nasal decongestant (i.e. adrenergic, steroids) within the last 7 days (or for more than 7 days) prior to initiating study treatment

Date of first enrolment
07/11/2022

Date of final enrolment
22/12/2022

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
The Virtual Clinical Trials Centre

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Yoshita Anandarajah, yoshita.x.anandarajah@haleon.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/02/2024	07/08/2025	Yes	No
Basic results			24/05/2024	No	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes