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Decongestant effect on the respiratory tract of subjects suffering from chronic obstructive pulmonary disease of a sterile class IIb medical device called UNCADEP® AEROSOL

Submission date
25/07/2024

Recruitment status
No longer recruiting

Registration date
13/08/2024

Overall study status
Completed

Last Edited
13/08/2024

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
UNCADEP® AEROSOL was marketed in Italy from 2017 until early 2023. Following the expiration of its CE certificate under Directive 93/42/EEC (MDD), it needs to be reintroduced to the market in compliance with the new Regulation (EU) 2017/745 (MDR), with some modifications to its properties: vial volume (from 2 ml to 5 ml); concentration of N-acetylcysteine (from 15% to 6%) and hyaluronic acid (from 0.1% to 0.05%); and molecular weight of hyaluronic acid (from 850-1150 kDa to 1100-1600 kDa).
As a result, this study was designed to reconfirm the effectiveness and safety of the reformulated device in the treatment of catarrhal conditions (inflammation) of the respiratory tract. Ultimately, the study aims to evaluate an inhalation preparation (hypertonic saline solution with N-acetylcysteine and hyaluronic acid) that offers a unique combination of mucolytic (breaking up mucus) and protective activities in the respiratory tract, which may be particularly beneficial for patients with COPD.

Who can participate?
Patients aged 40 years and over with COPD

Who does the study involve?
Patients are randomly allocated into two groups:
UNCADEP AEROSOL treatment group: COPD therapy integrated with UNCADEP® AEROSOL twice daily (morning and evening) for 10 days.
Control group: COPD therapy integrated with isotonic saline solution aerosol twice daily (morning and evening) for 10 days.
The patients are monitored 2 weeks before treatment, immediately before and after treatment, and 2 weeks after treatment.

What are the possible benefits and risks of participating?
The participants should benefit from the use of this medical device. It can help clear inflamed

airways, improve expectoration, and thus promote respiratory function. There are no particular risks associated with using this device; tolerable side effects are possible: bronchospasm (airway contractions), bronchial obstruction, rhinorrhea (runny nose), nausea, vomiting, stomatitis (inflamed mouth), skin rash and itching.

Where is the study run from?
Presidio Ospedaliero dei Pellegrini, Ambulatorio di Pneumologia (Italy)

When is the study starting and how long is it expected to run for?
January 2024 to September 2024

Who is funding the study?
Erbozeta S.p.A. (Italy)

Who is the main contact?
Dr Lucia Gallinaro, accettazioneobi.pellegrini@aslnapoli1centro.it

Contact information

Type(s)
Principal Investigator

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1/23 ASL NA 1

Study information

Scientific Title
Decongestant effect on the respiratory tract of subjects suffering from chronic obstructive pulmonary disease of a sterile class IIb medical device called UNCADEP® AEROSOL

Acronym
DECUNCA

Study objectives
The clinical investigation is aimed to systematically evaluate the clinical validity of preparation for inhalation use (hypertonic saline solution with N-acetylcysteine and hyaluronic acid) having a peculiar combination of mucolytic and protective activity in the airways, which can be particularly beneficial for patients with chronic obstructive pulmonary disease (COPD). This preparation is supposed to improve the respiratory function and quality of life of patients with COPD, without significant side effects.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/03/2024, Comitato etico territoriale Campania 1 (Fondazione Giovanni Pascale, via Mariano Semmola 52, Napoli, 80131, Italy; +39 (0)81 17770131; comitatoetico@istitutotumori.na.it), ref: Protocollo: 1/23 ASL NA 1

Study design
Pre-marketing controlled parallel-group randomized open single-center study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
The randomization starts after 14 days of run-in/enrollment phase.

The patients are randomly divided into two groups of 30 each by drawing envelopes containing randomisation numbers. The random number list was generated by an investigator with no clinical involvement in the trial.

UNCADEP® AEROSOL Treatment group (n = 30): COPD therapy integrated with UNCADEP® AEROSOL, 1 vial of 5 ml per nebulization session, two times a day (morning and evening), for 10 days.

Control (n = 30): COPD therapy integrated with isotonic saline solution aerosol, one vial of 5 ml per nebulization session, two times a day (morning and evening), for 10 days.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Device

Primary outcome measure
1. Objective respiratory function (FEV1) measured using spirometry at baseline and after 10 days of treatment
2. Serious adverse events in probable or certain correlation with the correct use of the device, recorded during the treatment period

Secondary outcome measures
1. Perceived respiratory function measured using mMRC score (5-point scale) by a questionnaire at baseline and after 10 days of treatment
2. Quality of life measured using CAT score (40-point scale) by a questionnaire at baseline and after 10 days of treatment

Overall study start date
15/01/2024

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Caucasian ethnicity
2. Ability to understand the Italian language
3. Age ≥40 years
4. COPD diagnosed, also by spirometry, for at least 12 months
5. COPD treated pharmacologically and stable for at least 4 weeks
6. COPD associated with expectoration difficulties

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Pregnancy and breastfeeding
2. Other kinds of chronic bronchopulmonary diseases, hemoptysis; current or past gastrointestinal ulcers
3. Renal or hepatic insufficiency
4. HIV infection
5. Neoplasms
6. Hypersensitivity to one or more components of the study products
7. Ongoing therapy with other mucoactive agents, antitussives, anticholinergics, or nitroglycerin

Date of first enrolment
19/06/2024

Date of final enrolment
06/09/2024

Locations

Countries of recruitment
Italy

Study participating centre
Presidio Ospedaliero dei Pellegrini, Ambulatorio di Pneumologia
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Sponsor information

Organisation
Erbozeta S.p.A.

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Sponsor type
Other

Website
https://www.erbozeta.com

Funder(s)

Funder type
Industry

Funder Name
Erbozeta S.p.A.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Giancarlo Tenore (giancarlo.tenore@unina.it). The data available are files (Word format) containing migraine diaries that were filled out by patients during the clinical trial.

IPD sharing plan summary

Available on request