Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Efficacy and Safety Study with Inhaled RVT-1601 for the Treatment of Persistent Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF): SCENIC Trial

Published: 07-03-2019
Last updated: 09-04-2024

To assess the efficacy of inhaled RVT-1601 in comparison with placebo following 12 weeks of treatment

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON48040

Source
ToetsingOnline

Brief title
RVT1601-CC-04 SCENIC Trial

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Idiopathic Pulmonary Fibrosis, persistent cough

Research involving
Human

Sponsors and support

Primary sponsor: Respivant Sciences GmBH
Source(s) of monetary or material Support: pharmaceutical company

Intervention

Keyword: Idiopathic pulmonary fibrosis, persistent cough, phase 2b

Outcome measures

Primary outcome

Change from baseline at the end of treatment in 24-hour average cough count

Secondary outcome

• Change from baseline at the end of treatment in cough severity as measured by VAS

• Change from baseline at the end of treatment in cough-specific QoL as measured by LCQ

• Proportion of responders with a minimum of 20% decrease from baseline at the end of treatment in 24-hour average cough count

• Change from baseline at the end of treatment in daytime average cough count

• Change from baseline at the end of treatment in nighttime average cough count

• Change from baseline at the end of treatment in ILD-specific QoL as measured by K-BILD

• Change from baseline at the end of treatment in respiratory-related QoL as measured by SGRQ

• Change from baseline at the end of treatment in dyspnea score as measured by SOBQ

• Change from baseline at the end of treatment in 6MWT

• Change from baseline at the end of treatment in FVC

• Proportion of subjects with no decline (i.e., < 5% decline), 5% - 10%

decline, and > 10% decline in FVC % predicted at the end of treatment

• Change from baseline at the end of treatment in airway and lung volumes as

measured by FRI

• Change from baseline at the end of treatment in average daily oxygen use

• Change from baseline at the end of treatment in exploratory biomarkers

Study description

Background summary

Idiopathic pulmonary fibrosis (IPF) is a progressive life-threatening disease that is characterized anatomically by scarring of the lungs and symptomatically by exertional dyspnea and dry cough.
Cough affects approximately three quarters of IPF cases.
Respivant is developing inhaled RVT-1601 for the treatment of persistent cough in patients with IPF.
RVT-1601 is a new inhalation formulation of cromolyn sodium delivered via the eFlow® Closed System (CS) nebulizer. Delivering RVT-1601 with the eFlow nebulizer system achieves higher lung deposition of cromolyn sodium relative to the currently marketed inhalation formulation of cromolyn sodium
Cromolyn sodium, with its well-established safety profile, is expected to play a therapeutic role in the treatment of persistent cough.

Study objective

To assess the efficacy of inhaled RVT-1601 in comparison with placebo following 12 weeks of treatment

Study design

a two part, multi-center, Phase 2b study

Intervention

RVT-1601 delivered via the eFlow® nebulizer for the Treatment of Persistent

Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF)

Study burden and risks

IPF is a progressive life-threatening disease that is characterized anatomically by scarring of the lungs and symptomatically by exertional dyspnea and cough, and has a median survival of 3-5 years.
Cromolyn sodium is considered a unique anti-asthma medication because of its extensive clinical and nonclinical record of safety. Historically, side effects are rare, minor, and reversible.
RVT-1601 formulation achieves significantly higher lung deposition and systemic bioavailability and, thus, a potential treatment of diseases and conditions requiring high tissue concentrations of cromolyn sodium.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or female subjects age 40 through 89 years, inclusive
2. Confirmed diagnosis of IPF with clinical features consistent with the current clinical practice guidelines for IPF
3. Presence of persistent cough for at least 8 weeks that is primarily due to IPF and not responsive to antitussive therapy
4. Daytime cough severity score of >=40 mm on a 100-mm VAS at the Screening Visit
5. 24-hour average cough count of at least 10 coughs per hour using an objective cough count monitor during Screening
6. Forced Vital Capacity (FVC) >= 45% predicted value within 4 weeks of the Screening Visit
7. Life expectancy of at least 12 months
8. Willing and able to follow the study required visits and assessments.
9. Willing and able to use the cough monitor for 24-hour periods at select study visits
11. Willing and able to provide written informed consent prior to study-related procedures

Exclusion criteria

1. Current or recent history of clinically significant medical condition, laboratory abnormality, or illness that could place the subject at risk or compromise the quality of the study data as determined by the investigator
2. Significant coronary artery disease (i.e., myocardial infarction within 6 months or unstable angina within 1 month of the Screening Visit)
3. An upper or lower respiratory tract infection within 4 weeks of the Screening Visit
4. Acute exacerbation of IPF within 6 months of the Screening Visit (Collard et al., 2016)
5. Lung transplantation expected within 12 months
6. Requiring supplemental O2 >= 4 litres/min to maintain peripheral arterial O2 saturation (SpO2) >= 88% at rest
7. History of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 2 years. This does not include minor surgical procedures for localized cancer (e.g., basal cell carcinoma, squamous cell, prostate carcinoma or cervical carcinoma in situ)
8. Current smoker (i.e., use of tobacco products within the last 3 months)
9. Current or recent history of drug or alcohol abuse within 12 months of the Screening Visit
10. Participation in any other investigational drug study within 4 weeks of the Screening Visit or within 5 times the elimination half-life of an

investigational drug
11. Use of the following drugs for cough management within 4 weeks of the Screening Visit: prednisone, opiates, baclofen, gabapentin, pregabalin, thalidomide, amitriptyline, inhaled corticosteroids, or inhaled bronchodilators
12. Use of ACE inhibitors or cromolyn sodium within 4 weeks of the Screening Visit
13. Females who are pregnant or breastfeeding, or if of child-bearing potential unwilling to practice acceptable means of birth control during the study (e.g., abstinence, combination barrier and spermicide, hormonal, or male partner sterilization)
14. History of hypersensitivity or intolerance to cromolyn sodium or its inactive ingredients

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-04-2019
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Cromolyn sodium [Disodium Cromoglycate]
Generic name:	RVT-1601

Ethics review

Approved WMO Date:	07-03-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-04-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-01-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	10-06-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-004447-23-NL
CCMO	NL68590.056.19