Trial record **1 of 1** for: ep-101-02

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Assessment of the Safety and Ability of a Once-a-day Dose of an Orally Inhaled Medicine [i.e., Glycopyrrolate Inhalation Solution = GIS] to Improve Airflow in the Lungs When Delivered Using an eFlow Nebulizer in Patients With Chronic Obstructive Pulmonary Disease (COPD)

ClinicalTrials.gov Identifier: NCT02948582

Recruitment Status: Completed
First Posted: October 28, 2016
Results First Posted: March 12, 2018
Last Update Posted: March 12, 2018

Sponsor:
Sunovion Respiratory Development Inc.

Information provided by (Responsible Party):
Sunovion Respiratory Development Inc.

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Triple (Participant, Care Provider, Investigator);

	Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Glycopyrrolate Inhalation Solution12.5µg Drug: Glycopyrrolate Inhalation Solution 50µg Drug: Glycopyrrolate Inhalation Solution 100µg Drug: Glycopyrrolate Inhalation Solution 200µg Drug: Glycopyrrolate Inhalation Solution 400µg Drug: Placebo 0.5mL

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
All enrolled subjects were randomized. all randomized subjects received at least one dose of study medication

Reporting Groups

	Description
Treatment Group 1	subjects received placebo, glycopyrrolate 400mcg, glycopyrrolate 50 mcg, glycopyrrolate 12.5 mcg, glycoyrrolate 200mcg, or glycopryrrolate 100mcg
Treatment Group 2	subjects received glycopyrrolate 12.5 mcg, glycopyrrolate 50 mcg, glycopryrrolate 100mcg, placebo, glycopyrrolate 200mcg, glycoyrrolate 400mcg, or placebo
Treatment Group 3	subjects received glycopyrrolate 50 mcg, Placebo, glycopyrrolate 200 mcg, glycopryrrolate 100mcg, glycopyrrolate 12.5mcg, or glycoyrrolate 400mcg
Treatment Group 4	subjects received glycopyrrolate 100 mcg, glycopyrrolate 200 mcg, glycopryrrolate 400mcg, placebo, glycopyrrolate 50mcg, or glycoyrrolate 12.5mcg
Treatment Group 5	subjects received glycopyrrolate 200 mcg, glycopyrrolate 12.5 mcg, placebo, glycopryrrolate 400mcg, placebo, glycopyrrolate 100mcg, or glycoyrrolate 50mcg
Treatment Group 6	subjects received glycopyrrolate 400 mcg, glycopyrrolate 100 mcg, glycopryrrolate 12.5mcg,

	glycopyrrolate 50mcg, placebo or glycoyrrolate 200mcg

Participant Flow for 12 periods

Period 1: Treatment Period 1

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	7	7	7	7	7
COMPLETED	7	7	7	7	7	7
NOT COMPLETED	0	0	0	0	0	0

Period 2: Washout Period 1

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	7	7	7	7	7
COMPLETED	7	5	7	7	7	6
NOT COMPLETED	0	2	0	0	0	1
Adverse Event	0	2	0	0	0	0
Protocol Violation	0	0	0	0	0	1

Period 3: Treatment Period 2

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	5	7	7	7	6
COMPLETED	7	5	7	7	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 4: Washout Period 2

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	5	7	7	7	6
COMPLETED	7	4	7	6	7	6

NOT COMPLETED	0	1	0	1	0	0
Adverse Event	0	1	0	0	0	0
personal reasons	0	0	0	1	0	0

Period 5: Treatment Period 3

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	4	7	6	7	6
COMPLETED	7	4	7	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 6: Washout Period 3

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	4	7	6	7	6
COMPLETED	7	4	7	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 7: Treatment Period 4

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	4	7	6	7	6
COMPLETED	7	4	7	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 8: Washout Period 4

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	7	4	7	6	7	6
COMPLETED	6	4	6	6	7	6

NOT COMPLETED	1	0	1	0	0	0
Adverse Event	1	0	1	0	0	0

Period 9: Treatment Period 5

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	6	4	6	6	7	6
COMPLETED	6	4	6	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 10: Washout Period 5

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	6	4	6	6	7	6
COMPLETED	6	4	6	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 11: Treatment Period 6

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	6	4	6	6	7	6
COMPLETED	6	4	6	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Period 12: Wshout Period 6

	Treatment Group 1	Treatment Group 2	Treatment Group 3	Treatment Group 4	Treatment Group 5	Treatment Group 6
STARTED	6	4	6	6	7	6
COMPLETED	6	4	6	6	7	6
NOT COMPLETED	0	0	0	0	0	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population same as safety population -not full analysis set

Reporting Groups

	Description
Total Participants	Intent to treat population same as safety population -not full analysis set

Baseline Measures

	Total Participants
Overall Participants Analyzed [Units: Participants]	**42**
Age [Units: Participants] Count of Participants	
<=18 years	**0** 0.0%
Between 18 and 65 years	**29** 69.0%
>=65 years	**13** 31.0%
Age [Units: Years] Mean (Standard Deviation)	**62.0 (6.99)**
Sex: Female, Male [Units: Participants] Count of Participants	
Female	**15** 35.7%
Male	**27** 64.3%
Ethnicity (NIH/OMB) [Units: Participants] Count of Participants	

Hispanic or Latino	**0** 0.0%
Not Hispanic or Latino	**42** 100.0%
Unknown or Not Reported	**0** 0.0%
Race (NIH/OMB) [Units: Participants] Count of Participants	
American Indian or Alaska Native	**0** 0.0%
Asian	**0** 0.0%
Native Hawaiian or Other Pacific Islander	**0** 0.0%
Black or African American	**0** 0.0%
White	**41** 97.6%
More than one race	**1** 2.4%
Unknown or Not Reported	**0** 0.0%
Region of Enrollment [Units: Participants] Count of Participants	
United Kingdom	**42**

Outcome Measures

Show All Outcome Measures

1. **Primary: Trough FEV1 (Change From Baseline) [Time Frame: 24hr post dose]**

   Show Outcome Measure 1

2. **Primary: Standardized FEV1AUC0-12 Area Under the FEV1 Curve From 0 to 12 Hours Post-dose (Actual and Change From Baseline). [Time Frame: 0-12h post dose]**

   Show Outcome Measure 2

3. **Primary: Standardized FEV1AUC12-24 Area Under the FEV1 Curve From 12 to 24 Hours Post- Dose (Actual and Change From Baseline). [Time Frame: 12-24h post dose]**

   Show Outcome Measure 3

4. **Primary: Standardized FEV1 AUC0-24 Area Under the FEV1 Curve From 0 to 24 Hours Post-dose (Actual and Change Baseline) [Time Frame: 0 to 24h]**

   Show Outcome Measure 4

5. Primary: Peak FEV1 (Change From Baseline and Percent Change) [Time Frame: 0-4h post dose]

Show Outcome Measure 5

6. Secondary: Cmax; Maximum Observed Plasma Concentration [Time Frame: 0 to 12 hour]

Show Outcome Measure 6

7. Secondary: Tmax; Time to Maximum Observed Plasma Concentration [Time Frame: 0 to 12 hours]

Show Outcome Measure 7

8. Secondary: t1/2; Plasma Half-life [Time Frame: 0 to 12 hour]

Show Outcome Measure 8

9. Secondary: AUC0-t; Area Under the Plasma Concentration-time Curve From Time Zero to Time of Last Measurable Drug Concentration. [Time Frame: 0 to 12 hour]

Show Outcome Measure 9

10. Secondary: AUC0-inf Area Under the Plasma Concentration-time Curve From Time Zero to Infinity [Time Frame: 0 to 12 hour]

Show Outcome Measure 10

11. Secondary: Number of Subjects Who Died, Number of Subjects With Treatment Emergent SAEs, Number of Subjects Who Discontinued Due to AE [Time Frame: Day 69 (includes dosing Day 1, washout Day 12, safety follow up Day 69)]

Show Outcome Measure 11

12. Secondary: Number of Subjects With Clinically Significant Abnormal Vital Signs Reported During the Study [Time Frame: 0-24 h]

Show Outcome Measure 12

13. Secondary: Number of Clinically Significant Abnormal Laboratory Results Reported During the Study [Time Frame: Day -14, Day 69]

Show Outcome Measure 13

14. Secondary: Number of Subjects With Clinically Significant ECG Parameters Reported During the Study [Time Frame: 0 to 24h]

Show Outcome Measure 14

15. Secondary: Percentage of Subjects With Treatment Emergent AEs [Time Frame: Day 69 (includes dosing Day 1, washout Day 12, safety follow up Day 69)]

Show Outcome Measure 15

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: In the event the Study is part of a multi-center study, the first publication of the results of the Study shall be made in conjunction with the results of other participating study sites as a multi-center publication; provided however, if a multi-center publication is not forthcoming within twenty-four (24) months following completion of the Study at all sites, Institution and Investigator shall be free to publish.

Results Point of Contact:

Name/Title: Respiratory Medical Director
Organization: Sunovion Pharmaceuticals Inc.
phone: 1-866-503-6351

Publications of Results:

Leaker BR, Barnes PJ, Jones CR, Tutuncu A, Singh D. Efficacy and safety of nebulized glycopyrrolate for administration using a high efficiency nebulizer in patients with chronic obstructive pulmonary disease. Br J Clin Pharmacol. 2015 Mar;79(3):492-500. doi: 10.1111/bcp.12517.

Responsible Party:	Sunovion Respiratory Development Inc.
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Results First Posted:	March 12, 2018
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