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Trial record **1 of 1** for: ep-101-03

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Study to Investigate the Dose Response, Safety and Efficacy of Nebulized EP-101(SUN101) in Patients With Chronic Obstructive Pulmonary Disease (COPD): GOLDEN-1 Study

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT01426009

Recruitment Status : Completed
First Posted : August 30, 2011
Results First Posted : May 7, 2018
Last Update Posted : May 9, 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: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor); Primary Purpose: Treatment

Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: EP-101 via nebulizer (eFlow®) 25 ug Drug: EP-101 via nebulizer (eFlow®) 50 ug Drug: EP-101 via nebulizer (eFlow®) 100 ug Drug: Placebo EP-101 Drug: Tiotropium bromide via (Spiriva® Handihaler®) Drug: Ipratropium bromide Inhalation Solution via Handihaler® DPI Drug: EP-101 via nebulizer (eFlow®) 200 ug

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
One randomized subject did not receive any study medication.

Reporting Groups

	Description
Total	total subjects which includes:EP-101 via nebulizer (eFlow®), Tiotropium bromide via (Spiriva® Handihaler®), Ipratropium bromide Inhalation Solution via Handihaler® DPI , and Placebo EP-101",

Participant Flow for 8 periods

Period 1: Period 1-First Intervention (7 Days)

	Total
STARTED	**139**
EP-101 Via Nebulizer	**23**
EP-101 Via Nebulizer	**24**
EP-101 Via Nebulizer	**22**
EP-101 Via Nebulizer	**23**

Ipratropium Bromide	23
Placebo	24
COMPLETED	137
NOT COMPLETED	2
Adverse Event	1
Personal Reasons	1

Period 2: Washout 1

	Total
STARTED	137
COMPLETED	135
NOT COMPLETED	2
Withdrawal by Subject	1
Personal Reasons	1

Period 3: Period 2-Second Intervention (7 Days)

	Total
STARTED	135
EP-101 Via Nebulizer	22
EP-101 Via Nebulizer	24
EP-101 Via Nebulizer	24
EP-101 Via Nebulizer	23
Ipratropium Bromide	21
Placebo	21
COMPLETED	130
NOT COMPLETED	5
Adverse Event	4
personal reasons	1

Period 4: Washout 2

	Total
STARTED	130

COMPLETED	**129**
NOT COMPLETED	**1**
electrive surgery	**1**

Period 5: Period 3-Third Intervention (7 Days)

	Total
STARTED	**129**
EP-101 Via Nebulizer	**19**
EP-101 Via Nebulizer	**23**
EP-101 Via Nebulizer	**22**
EP-101 Via Nebulizer	**20**
Ipratropium Bromide	**23**
Placebo	**22**
COMPLETED	**129**
NOT COMPLETED	**0**

Period 6: Washout 3

	Total
STARTED	**129**
COMPLETED	**128**
NOT COMPLETED	**1**
personal reasons	**1**

Period 7: Period 4-Fourth Intervention (7 Days)

	Total
STARTED	**128**
EP-101 Via Nebulizer	**10**
EP-101 Via Nebulizer	**7**
EP-101 Via Nebulizer	**8**
EP-101 Via Nebulizer	**9**
Ipratropium Bromide	**8**

Tiotropium Bromide	**76**
Placebo	**10**
COMPLETED	**127**
NOT COMPLETED	**1**
personal reasons	**1**

Period 8: Washout 4

	Total
STARTED	**127**
COMPLETED	**126**
NOT COMPLETED	**1**
Lost to Follow-up	**1**

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.
modified Intent to Treat population for analysis set

Reporting Groups

	Description
Total Particiants	total of all participants in the study

Baseline Measures

	Total Particiants
Overall Participants Analyzed [Units: Participants]	**139**
Age [Units: Participants] Count of Participants	

<=18 years	**0** 0.0%
Between 18 and 65 years	**88** 63.3%
>=65 years	**51** 36.7%
Age [Units: Years] Mean (Standard Deviation)	**61.4 (8.11)**
Sex: Female, Male [Units: Participants] Count of Participants	
Female	**78** 56.1%
Male	**61** 43.9%
Ethnicity (NIH/OMB) [Units: Participants] Count of Participants	
Hispanic or Latino	**1** 0.7%
Not Hispanic or Latino	**138** 99.3%
Unknown or Not Reported	**0** 0.0%
Race (NIH/OMB) [Units: Participants] Count of Participants	
American Indian or Alaska Native	**1** 0.7%
Asian	**0** 0.0%
Native Hawaiian or Other Pacific Islander	**0** 0.0%
Black or African American	**4** 2.9%
White	**134** 96.4%
More than one race	**0** 0.0%
Unknown or Not Reported	**0** 0.0%
Region of Enrollment [Units: Participants] Count of Participants	
United States	**120**
United Kingdom	**19**

Outcome Measures

Show All Outcome Measures

1. Primary: Mean Change in 24 Post Dose Trough Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Day 1 and Day 7]

   Show Outcome Measure 1

2. Primary: Standardized Change in FEV1 Area Under the Curve (AUC) (0-12hr , 12-24hr, 0-24hr) on Day 1 and Day 7 [Time Frame: Day 1 and Day 7]

   Show Outcome Measure 2

3. Secondary: Peak FEV1 (Maximum FEV1 During the First 4 Hours Post-dose on Day 1 and Day 7) [Time Frame: Day 1 and Day 7]

   Show Outcome Measure 3

4. Secondary: Treatment Responders (Number of Subjects With Clinically Meaningful Change From Pre-dose in Trough FEV1 on Day 1 and Day 7) [Time Frame: Day 1 and Day 7]

   Show Outcome Measure 4

5. Secondary: Number of Participants With Adverse Events, Vital Signs, and Clinically Significant Abnormal ECG Values and Laboratory Tests [Time Frame: Day 1 through Day 7]

   Show Outcome Measure 5

6. Secondary: Rescue Medication Use [Time Frame: Day 1 through Day 7]

   Show Outcome Measure 6

7. Secondary: Treatment Responders (Percentage of Subjects With Clinically Meaningful Change From Pre-dose in Trough FEV1 on Day 1 and Day 7) [Time Frame: Day 1 and Day 7]

   Show Outcome Measure 7

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.
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Responsible Party:	Sunovion Respiratory Development Inc.
ClinicalTrials.gov Identifier:	NCT01426009 History of Changes
Other Study ID Numbers:	**EP-101-03**
First Submitted:	August 29, 2011
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