Trial record **1 of 1** for: CQVA149A2203

Previous Study | Return to List | Next Study

Safety and Tolerability of QVA149 (Indacaterol/Glycopyrrolate) Compared to Placebo and to Indacaterol in Patients With Moderate to Severe Stable Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00558285

First received: November 12, 2007
Last updated: November 28, 2012
Last verified: November 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: October 23, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease (COPD)
Interventions:	Drug: indacaterol/glycopyrrolate Drug: indacaterol Drug: glycopyrrolate Drug: placebo

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
No text entered.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600 µg/100 µg	Two capsules indacaterol/glycopyrrolate 300 µg/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300 µg/100 µg	One capsule indacaterol/glycopyrrolate 300 µg/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150 µg/100 µg	One capsule indacaterol/glycopyrrolate 150 µg/50 µg and one capsule 50µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days.

	The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Participant Flow: Overall Study

	Indacaterol/Glycopyrrolate 600 µg/100 µg	Indacaterol/Glycopyrrolate 300 µg/100 µg	Indacaterol/Glycopyrrolate 150 µg/100 µg	Indacaterol 300 µg	Placebo
STARTED	50	51	51	52	53
Safety: Received Study Drug	49	51	51	51	53
COMPLETED	44	48	46	48	49
NOT COMPLETED	6	3	5	4	4
Adverse Event	1	1	4	1	2
Abnormal test procedure result(s)	1	0	0	0	0
Subject withdrew consent	2	0	1	1	1
Lost to Follow-up	1	1	0	0	0
Administrative problems	0	0	0	1	1
Protocol deviation	1	1	0	1	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.
No text entered.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol/Glycopyrrolate 600/100 µg	**Indacaterol/Glycopyrrolate 300/100 µg**	**Indacaterol/Glycopyrrolate 150/100 µg**	**Indacaterol 300 µg**	**Placebo**	**Total**

Number of Participants [units: participants]	**49**	**51**	**51**	**51**	**53**	**255**
Age [1] [units: years] Mean (Standard Deviation)	**65.7 (9.34)**	**63.7 (8.94)**	**60.9 (8.58)**	**64.5 (9.75)**	**64.3 (8.95)**	**63.8 (9.19)**
Gender [units: participants]						
Female	**11**	**10**	**15**	**10**	**14**	**60**
Male	**38**	**41**	**36**	**41**	**39**	**195**

[1] Overall Number of Baseline Participants is based on the Safety Population

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Mean 24 Hour Heart Rate at Day 14 [Time Frame: Baseline, Day 14]

Measure Type	Primary
Measure Title	Change From Baseline in Mean 24 Hour Heart Rate at Day 14
Measure Description	Heart rate was assessed by Holter monitoring and was measured over a 24 hour period at day 14. Heart rate was defined as the average value over the 24 hour monitoring period. The baseline measurement was the average heart rate taken from the 24 hour Holter monitoring period performed at screening or the last 24-hour period before taking the first dose of study drug. Least square means are based on the analysis of covariance: 24 hours mean heart rate = center + treatment + baseline value + Forced Expiratory Volume in one second (FEV1) before inhalation of salbutamol/albuterol + FEV1 30 min post salbutamol/albuterol + error.
Time Frame	Baseline, Day 14
Safety Issue	No

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.
Safety Population includes all patients who received at least one dose of study drug. Participants with less than 18 hours quality recording time data were excluded from this analysis.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate	**Indacaterol/Glycopyrrolate**	**Indacaterol/Glycopyrrolate**	**Indacaterol**	**Placebo**

	600/100 µg	300/100 µg	150/100 µg	300 µg	
Number of Participants Analyzed [units: participants]	**39**	**45**	**40**	**42**	**45**
Change From Baseline in Mean 24 Hour Heart Rate at Day 14 [units: beats per minute] Least Squares Mean (Standard Error)	**-0.113 (0.9967)**	**0.787 (0.8975)**	**-0.230 (0.9567)**	**0.240 (0.9373)**	**0.170 (0.8760)**

No statistical analysis provided for Change From Baseline in Mean 24 Hour Heart Rate at Day 14

2. Secondary: Change From Baseline in Mean 24 Hour Heart Rate at Day 1 [Time Frame: Baseline, Day 1]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean 24 Hour Heart Rate at Day 1
Measure Description	Heart rate was assessed by Holter monitoring and was measured over a 24 hour period at day 1. Heart rate was defined as the average value over the 24 hour monitoring period. The baseline measurement was the average heart rate taken from the 24 hour Holter monitoring period performed at screening or the last 24-hour period before taking the first dose of study drug. Least squares means are based on the analysis of covariance: 24 hours mean heart rate = center + treatment + baseline value + Forced Expiratory Volume in one second (FEV1) before inhalation of salbutamol/albuterol + FEV1 30 min after inhalation of salbutamol/albuterol + error.
Time Frame	Baseline, Day 1
Safety Issue	No

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.

Safety Population includes all patients who received at least one dose of study drug. Participants with less than 18 hours quality recording time data were excluded from this analysis.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**45**	**46**	**47**	**48**	**47**

Change From Baseline in Mean 24 Hour Heart Rate at Day 1 [units: beats per minute] Least Squares Mean (Standard Error)	**-2.877 (0.8790)**	**-2.770 (0.8244)**	**-0.547 (0.8208)**	**-1.849 (0.8211)**	**-0.329 (0.8181)**

No statistical analysis provided for Change From Baseline in Mean 24 Hour Heart Rate at Day 1

3. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Day 14 [Time Frame: Day 1, Day 14]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Day 14
Measure Description	Spirometry testing was performed in accordance with American Thoracic Society standards. Trough FEV1 was defined as the mean of two measurements at 23 hours 15 minutes and 23 hour 45 minutes post dosing. Baseline is defined as the mean of the two values taken at 45 minutes and 15 minutes prior to dosing at day 1. Least square means are based on the analysis of covariance: response variable=center + treatment + baseline value + Forced Expiratory Volume in one second (FEV1) before inhalation of salbutamol/albuterol + FEV1 30 minutes post inhalation of salbutamol/albuterol.
Time Frame	Day 1, Day 14
Safety Issue	No

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 includes all randomized patients. Any spirometric data collected less than six hours after rescue medication use was regarded as missing.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**50**	**51**	**51**	**52**	**53**
Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Day 14 [units: Liters] Least Squares Mean					

(Standard Error)					
Day 1	**1.59 (0.024)**	**1.51 (0.023)**	**1.50 (0.022)**	**1.44 (0.023)**	**1.27 (0.022)**
Day 14	**1.61 (0.027)**	**1.52 (0.025)**	**1.50 (0.026)**	**1.46 (0.025)**	**1.31 (0.024)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Day 14

4. Secondary: Trough Forced Vital Capacity (FVC) at Day 1 and Day 14 [Time Frame: Day 1 and Day 14]

Measure Type	Secondary
Measure Title	Trough Forced Vital Capacity (FVC) at Day 1 and Day 14
Measure Description	Spirometry testing was performed in accordance with American Thoracic Society standards. Trough FVC was defined as the mean of two measurements at 23 hours 15 minutes and the 23 hours 45 minutes post dosing. Baseline was defined as the mean of the two values taken at 45 minutes and 15 minutes prior to dosing at day 1. Analysis of covariance: FVC parameter = center + treatment + baseline FVC + FEV1 before inhalation of salbutamol/albuterol + FEV1 30 min after inhalation of salbutamol/albuterol + error.
Time Frame	Day 1 and Day 14
Safety Issue	No

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.
Participants from the Intent-to-treat Population (all randomized patients) with data available at the given time-point. Any spirometric data collected less than six hours after rescue medication use was regarded as missing.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**48**	**48**	**51**	**49**	**52**
Trough Forced Vital Capacity (FVC) at Day 1 and Day 14 [units: Liters] Least Squares Mean (Standard Error)					

Day 1	**3.151 (0.0437)**	**3.029 (0.0421)**	**3.000 (0.0403)**	**2.924 (0.0419)**	**2.634 (0.0402)**
Day 14 (n=42, 45, 44, 48, 47)	**3.134 (0.0469)**	**3.042 (0.0446)**	**2.952 (0.0455)**	**2.901 (0.0442)**	**2.726 (0.0424)**

No statistical analysis provided for Trough Forced Vital Capacity (FVC) at Day 1 and Day 14

5. Secondary: Change From Baseline in QTc (Fridericia's Formula) at Day 1 [Time Frame: Baseline, Day 1]

Measure Type	Secondary
Measure Title	Change From Baseline in QTc (Fridericia's Formula) at Day 1
Measure Description	The change from baseline in QTc at 30 minutes, 4 hours and 23 hours 45 minutes post dose on day 1. QT calculated (QTc) was calculated from the QT interval and RR (in seconds) using Fridericia's formula: QTc = QT / 3√ RR. Least square means are based on the analysis of covariance: response variable = center + treatment + baseline value + FEV1 before inhalation of salbutamol/albuterol + FEV1 30 min post inhalation of salbutamol/albuterol.
Time Frame	Baseline, Day 1
Safety Issue	No

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.
Safety Population includes all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in

	the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**49**	**51**	**51**	**51**	**53**
Change From Baseline in QTc (Fridericia's Formula) at Day 1 [units: milliseconds] Least Squares Mean (Standard Error)					
				3.1 (1.47)	**-1.6**

30 minutes	**1.6 (1.58)**	**1.2 (1.48)**	**1.4 (1.50)**		**(1.44)**
4 hours	**2.8 (1.67)**	**0.5 (1.56)**	**2.4 (1.58)**	**1.1 (1.60)**	**-2.3 (1.52)**
23 hours 45 minutes	**2.7 (1.77)**	**-1.7 (1.66)**	**-0.1 (1.67)**	**-2.1 (1.71)**	**-2.3 (1.62)**

No statistical analysis provided for Change From Baseline in QTc (Fridericia's Formula) at Day 1

6. Secondary: Change From Baseline in QTc (Fridericia's Formula) at Day 7 [Time Frame: Baseline, Day 7]

Measure Type	Secondary
Measure Title	Change From Baseline in QTc (Fridericia's Formula) at Day 7
Measure Description	The change from baseline in QTc at 30 minutes and 2 hours post dose on day 7. QT calculated (QTc) was calculated from the QT interval and RR (in seconds) using Fridericia's formula: QTc = QT / 3√ RR. Least square means are based on the analysis of covariance: response variable = center + treatment + baseline value + FEV1 before inhalation of salbutamol/albuterol + FEV1 30 min post inhalation of salbutamol/albuterol.
Time Frame	Baseline, Day 7
Safety Issue	No

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.
Safety Population includes all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in

	the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	**Indacaterol/Glycopyrrolate 300/100 µg**	**Indacaterol/Glycopyrrolate 150/100 µg**	**Indacaterol 300 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**49**	**51**	**51**	**51**	**53**
Change From Baseline in QTc (Fridericia's Formula) at Day 7 [units: milliseconds] Least Squares Mean (Standard Error)					
				-1.3	**-2.2**

30 minutes	**4.1 (1.91)**	**-0.9 (1.74)**	**0.5 (1.78)**	**(1.79)**	**(1.70)**
2 hours	**2.6 (2.17)**	**-1.2 (1.98)**	**1.6 (2.02)**	**-1.6 (2.00)**	**-2.8 (1.94)**

No statistical analysis provided for Change From Baseline in QTc (Fridericia's Formula) at Day 7

7. Secondary: Change From Baseline in QTc (Fridericia's Formula) at Day 14 [Time Frame: Baseline, Day 14]

Measure Type	Secondary
Measure Title	Change From Baseline in QTc (Fridericia's Formula) at Day 14
Measure Description	The change from baseline in QTc at 30 minutes, 4 hours and 23 hours 45 minutes post dose on day 14. QT calculated (QTc) was calculated from the QT interval and RR (in seconds) using Fridericia's formula: QTc = QT / 3√ RR. Least square means are based on the analysis of covariance: response variable = center + treatment + baseline value + FEV1 before inhalation of salbutamol/albuterol + FEV1 30 minutes post inhalation of salbutamol/albuterol.
Time Frame	Baseline, Day 14
Safety Issue	No

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.
Safety Population includes all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Measured Values

	Indacaterol/Glycopyrrolate 600/100 µg	**Indacaterol/Glycopyrrolate 300/100 µg**	**Indacaterol/Glycopyrrolate 150/100 µg**	**Indacaterol 300 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**49**	**51**	**51**	**51**	**53**
Change From Baseline in QTc (Fridericia's Formula) at Day 14 [units: milliseconds] Least Squares Mean (Standard Error)					
30 minutes	**2.4 (1.79)**	**-0.6 (1.64)**	**1.6 (1.70)**	**-1.2 (1.69)**	**0.2 (1.62)**
				-2.6	**-0.1**

4 hours	**2.8 (1.90)**	**-0.1 (1.76)**	**3.1 (1.85)**	**(1.81)**	**(1.73)**
23 hours 45 minutes	**0.5 (1.94)**	**-2.9 (1.81)**	**0.4 (1.95)**	**-3.6 (1.88)**	**-1.6 (1.77)**

No statistical analysis provided for Change From Baseline in QTc (Fridericia's Formula) at Day 14

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days.

	The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol /albuterol as rescue medication was permitted throughout the study.

Serious Adverse Events

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Total, serious adverse events					
# participants affected / at risk	**2/49 (4.08%)**	**0/51 (0.00%)**	**2/51 (3.92%)**	**0/51 (0.00%)**	**1/53 (1.89%)**
Blood and lymphatic system disorders					
Anaemia † [1]					
# participants affected / at risk	**0/49 (0.00%)**	**0/51 (0.00%)**	**1/51 (1.96%)**	**0/51 (0.00%)**	**0/53 (0.00%)**
Cardiac disorders					
Atrial fibrillation † [1]					
# participants affected / at risk	**1/49 (2.04%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**0/53 (0.00%)**
Ventricular tachycardia † [1]					
# participants affected / at risk	**0/49 (0.00%)**	**0/51 (0.00%)**	**1/51 (1.96%)**	**0/51 (0.00%)**	**0/53 (0.00%)**
Investigations					
Blood potassium					

increased † 1					
# participants affected / at risk	**1/49 (2.04%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**0/53 (0.00%)**
Respiratory, thoracic and mediastinal disorders					
Chronic obstructive pulmonary disease † 1					
# participants affected / at risk	**0/49 (0.00%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**0/51 (0.00%)**	**1/53 (1.89%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol/Glycopyrrolate 600/100 µg	Two capsules indacaterol/glycopyrrolate 300/50 µg delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.

Indacaterol/Glycopyrrolate 300/100 µg	One capsule indacaterol/glycopyrrolate 300/100 µg and one placebo capsule delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol/Glycopyrrolate 150/100 µg	One capsule indacaterol/glycopyrrolate 150/50 µg and one capsule 50 µg glycopyrrolate delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Indacaterol 300 µg	One capsule indacaterol 300 µg and one placebo capsule delivered via s single dose dry powder inhaler in the morning for 14 days. The use of salbutamol/albuterol as rescue medication was permitted throughout the study.
Placebo	Two placebo capsules delivered via a single dose dry powder inhaler in the morning for 14 days. The use of salbutamol /albuterol as rescue medication was permitted throughout the study.

Other Adverse Events

	Indacaterol/Glycopyrrolate 600/100 µg	Indacaterol/Glycopyrrolate 300/100 µg	Indacaterol/Glycopyrrolate 150/100 µg	Indacaterol 300 µg	Placebo
Total, other (not including serious) adverse events					
# participants affected / at risk	**5/49 (10.20%)**	**6/51 (11.76%)**	**10/51 (19.61%)**	**7/51 (13.73%)**	**4/53 (7.55%)**
Gastrointestinal disorders					
Dry mouth † [1]					
# participants affected / at risk	**3/49 (6.12%)**	**1/51 (1.96%)**	**3/51 (5.88%)**	**0/51 (0.00%)**	**0/53 (0.00%)**
Nervous system					

disorders					
Headache † 1					
# participants affected / at risk	**2/49 (4.08%)**	**1/51 (1.96%)**	**2/51 (3.92%)**	**3/51 (5.88%)**	**1/53 (1.89%)**
Respiratory, thoracic and mediastinal disorders					
Chronic obstructive pulmonary disease † 1					
# participants affected / at risk	**0/49 (0.00%)**	**2/51 (3.92%)**	**5/51 (9.80%)**	**1/51 (1.96%)**	**1/53 (1.89%)**
Cough † 1					
# participants affected / at risk	**3/49 (6.12%)**	**2/51 (3.92%)**	**3/51 (5.88%)**	**2/51 (3.92%)**	**1/53 (1.89%)**
Vascular disorders					
Hypertension † 1					
# participants affected / at risk	**0/49 (0.00%)**	**3/51 (5.88%)**	**1/51 (1.96%)**	**1/51 (1.96%)**	**1/53 (1.89%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

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:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party: Novartis

ClinicalTrials.gov Identifier:	NCT00558285 History of Changes
Other Study ID Numbers:	**CQVA149A2203**
Study First Received:	November 12, 2007
Results First Received:	October 23, 2012
Last Updated:	November 28, 2012
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration Belgium: Federal Agency for Medicinal Products and Health Products Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: The Italian Medicines Agency Spain: Spanish Agency of Medicines Turkey: Ministry of Health