QVA149 Versus Fluticasone/Salmeterol in Patients With Chronic Obstructive Pulmonary Disease (COPD) (ILLUMINATE)

This study is currently recruiting participants.
Verified on March 2011 by Novartis

First Received on March 11, 2011. Last Updated on March 14, 2011

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>Novartis Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information provided by:</td>
<td>Novartis</td>
</tr>
<tr>
<td>ClinicalTrials.gov Identifier:</td>
<td>NCT01315249</td>
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</tbody>
</table>

**Purpose**

The purpose of this study is to compare the efficacy and safety/tolerbility of QVA149 (fixed-dose combination of indacaterol and NVA237) with fluticasone/salmeterol over a 26-week period in patients with moderate to severe COPD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Obstructive Airway Disease</td>
<td>Drug: QVA149 Drug: fluticasone/salmeterol</td>
<td>Phase III</td>
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</tbody>
</table>

Study Type: Interventional

Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A 26-week Treatment, Multi-center, Randomized, Double-blind, Double Dummy, Parallel-group Study to Assess the Efficacy, Safety and Tolerability of QVA149 Compared to Fluticasone/Salmeterol in Patients With Moderate to Severe COPD

Resource links provided by NLM:

[MedlinePlus](https://medlineplus.gov) related topics: [COPD (Chronic Obstructive Pulmonary Disease)](https://medlineplus.gov/ency/article/000916.htm)
Further study details as provided by Novartis:

Primary Outcome Measures:
- To demonstrate the superiority of once-daily QVA149 as compared to twice-daily fluticasone/salmeterol in terms of forced expiratory volume in one second (FEV1) area under the curve for 0-12 hours (AUC0-12h) in patients with moderate to severe COPD. [Time Frame: 26 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:
- To evaluate the effect of QVA149 as compared to fluticasone/salmeterol in terms of standardized FEV1 AUC0-12h. [Time Frame: 12 weeks] [Designated as safety issue: No]
- To evaluate the effect of QVA149 as compared to fluticasone/salmeterol in terms of safety and tolerability as measured by adverse events [Time Frame: 26 weeks] [Designated as safety issue: Yes]

Estimated Enrollment: 522

Study Start Date: March 2011

Estimated Primary Completion Date: March 2012 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>QVA149: Experimental QVA149, delivered once daily via single-dose dry powder inhaler (SDDPI) Intervention: Drug: QVA149</td>
<td>Drug: QVA149</td>
</tr>
<tr>
<td>fluticasone/salmeterol (Seretide): Active Comparator fluticasone/salmeterol (Seretide®) delivered twice daily via the Accuhaler® Intervention: Drug: fluticasone/salmeterol</td>
<td>Drug: fluticasone/salmeterol</td>
</tr>
</tbody>
</table>

**Eligibility**

Ages Eligible for Study: 40 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Criteria

Inclusion Criteria:
- Smoking history of at least 10 pack years
- Diagnosis of COPD (moderate-to-severe as classified by the Global Initiative for Chronic Obstructive Lung Disease [GOLD] Guidelines, 2009)
- Post-bronchodilator FEV1 < 80% and ≥ 40% of the predicted normal value and post-bronchodilator FEV1/FVC (forced vital capacity) <70%

Exclusion Criteria:
- Patients who have had a COPD exacerbation that required treatment with antibiotics, systemic steroids (oral or intravenous) or hospitalization in the last year.
- Patients requiring long term oxygen therapy on a daily basis for chronic hypoxemia.
- Patients who have had a respiratory tract infection within 4 weeks prior to Visit 1.
- Patients with concomitant pulmonary disease
- Patients with a history of asthma
- Any patient with lung cancer or a history of lung cancer
- Patients with a history of certain cardiovascular co-morbid conditions

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01315249

Contacts

Contact: Novartis Pharmaceuticals +41-61-324-1111

Show 69 Study Locations

Sponsors and Collaborators
Novartis Pharmaceuticals

Investigators
Study Director: Novartis Pharmaceuticals Novartis Pharmaceuticals

More Information

No publications provided

Responsible Party: Novartis Pharmaceuticals (External Affairs)
ClinicalTrials.gov Identifier: NCT01315249 History of Changes
Other Study ID Numbers: CQVA149A2313, 2010-023621-37
Study First Received: March 11, 2011
Last Updated: March 14, 2011
Health Authority: United States: Food and Drug Administration; Belgium:
Keywords provided by Novartis:
QVA149
indacaterol
NVA237
COPD
Fluticasone/Salmeterol

Additional relevant MeSH terms:
Lung Diseases
Pulmonary Disease, Chronic Obstructive
Lung Diseases, Obstructive
Respiratory Tract Diseases
Salmeterol
Albuterol
Fluticasone
Fluticasone, salmeterol drug combination
Adrenergic beta-2 Receptor Agonists
Adrenergic beta-Agonists

Physiological Effects of Drugs
Bronchodilator Agents
Autonomic Agents
Peripheral Nervous System Agents
Anti-Asthmatic Agents
Respiratory System Agents
Therapeutic Uses
Tocolytic Agents
Reproductive Control Agents
Dermatologic Agents