

Study of the impact of indacaterol on the individual lives and health status of patients with chronic obstructive pulmonary disease (COPD)

Submission date 11/04/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/05/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 07/06/2017	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Clinical studies provide useful information regarding both the safety and effectiveness of medicines, but clinical trial settings are not always as close to a real-world setting as they could be, often due to the excluding of patients taking specific medications or with other specific conditions, and the patients are also often intensively monitored throughout the study. Indacaterol is a drug used for the treatment of chronic obstructive pulmonary disease (COPD). It is taken once a day to open up the airways that will have become narrowed as part of the disease process of COPD. The aim of this study is to measure the impact of indacaterol on individual patients in a real-world setting, where the patients have been prescribed indacaterol as their standard therapy following a clinical assessment for their COPD.

Who can participate?

The study is open to patients in selected GP practices in the UK that have chosen to participate. Patients must be aged over 18 and have been prescribed indacaterol for COPD.

What does the study involve?

This study uses data from routine clinical examinations. In addition to standard measurements, patients will also be requested to complete two straightforward questionnaires at specified timepoints during the study and will also be requested to rate their overall opinion of the effectiveness of indacaterol at the end of the study. Patients in the study will be monitored for a total of 6 months, with a visit between 6 and 8 weeks after the start of the study.

What are the possible benefits and risks of participating?

There may be a potential benefit for participating patients in terms of improved monitoring of their COPD, though this study has been designed to be close to the standard monitoring of COPD patients starting a new medication. The only potential impact for patients is the short amount of time required to complete the two short questionnaires.

Where is the study run from?
Novartis Pharmaceuticals UK Ltd.

When is the study starting and how long is it expected to run for?
From April 2012 to August 2013.

Who is funding the study?
Novartis Pharmaceuticals UK Ltd.

Who is the main contact?
Dr Amr Radwan

Contact information

Type(s)
Scientific

Contact name
Dr Amr Radwan

Contact details
Novartis Pharmaceuticals UK Ltd
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United Kingdom
GU16 7SR

Additional identifiers

Protocol serial number
CQAB149BGB01

Study information

Scientific Title
INdacaterol effect on Health status in COPD: A real Life patient Experience prospective observational study (INHALE)

Acronym
INHALE

Study objectives
Whilst there have been clinical trials of indacaterol showing the improvement of objective measures of COPD such as Forced expiratory volume in one second (FEV1) and dyspnoea score, there is to date no information on its impact on individual patient lives in the real world. Novartis are keen to undertake a prospective observational study of the impact of indacaterol on individual patient lives in the real world by looking at patient experience in the nonRCT population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This observational study will be submitted for ethical review via the National Research Ethics Service (NRES) and appropriate PCT (or equivalent) and practice research governance approval will be obtained before the study commences in each location. Patient consent will be sought for participation in the study.

Study design

Prospective observational multicentre research study in GP practices clustered within up to 10 UK primary care trusts (PCTs)

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Patients in the study will have been prescribed indacaterol as part of routine clinical practice. Patients will be asked to complete the COPD Assessment Test (CAT) at baseline, 6-8 weeks and 6 months after initiation, a life impact questionnaire at 6-8 weeks after initiation and a Global Evaluation of Treatment Effectiveness (GETE) questionnaire at 6 months after initiation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Absolute CAT scores and mean standard deviation (SD) change from baseline in CAT score at 68 weeks after initiation of indacaterol

Key secondary outcome(s)

1. Mean (SD) change from baseline in CAT score at 6 months after initiation of indacaterol
2. Qualitative description of the impact of indacaterol on the patients' life at 68 weeks after initiation of indacaterol
3. Distribution and summary statistics of physician GETE at 68 weeks and 6 months after initiation of indacaterol
4. Distribution and summary statistics of patient GETE at 6 months after initiation of indacaterol
5. Distribution and summary statistics of FEV1 throughout the observation period
6. Distribution and summary statistics of MRC dyspnoea scores throughout the observation period
7. Description of study sample at baseline

Completion date

01/10/2013

Eligibility

Key inclusion criteria

1. Patients with active diagnosis of COPD, confirmed by spirometry, documented in medical notes
2. Patients who are newly prescribed indacaterol as part of routine clinical practice

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who have previously received maintenance therapy for COPD symptoms e.g. Long acting beta agonists (LABAs), long acting antimuscarinics (LAMAs), LABA + inhaled corticosteroid (ICS)
2. Patients unable or unwilling to consent to participation in the study
3. Patients unable or unwilling to complete the study questionnaires
4. Patients who have participated in any interventional clinical trial for indacaterol
5. Patients who have previously been prescribed indacaterol

Date of first enrolment

01/05/2012

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Novartis Pharmaceuticals UK Ltd

Frimley

United Kingdom

GU16 7SR

Sponsor information

Organisation

Novartis Pharmaceuticals UK Ltd (UK)

ROR

<https://ror.org/039s6n838>

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration