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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

Registration date
10/05/2012

Overall study status
Completed

Last Edited
07/06/2017

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 andwill 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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Frimley
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GU16 7SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 btained 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

Secondary study design
Other

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

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

Overall study start date
01/05/2012

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 newlyprescribed indacaterol as part of routine clinical practice

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200 patients

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
England

United Kingdom

Study participating centre
Novartis Pharmaceuticals UK Ltd
Frimley
United Kingdom
GU16 7SR

Sponsor information

Organisation
Novartis Pharmaceuticals UK Ltd (UK)

Sponsor details
200 Frimley Business Park
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GU16 7SR

Sponsor type
Industry

ROR
https://ror.org/039s6n838

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration