A randomized, parallel group study to evaluate the effect of Umeclidinium (UMEC) added to Inhaled corticosteroid/ long-acting beta-agonist combination therapy in subjects with Chronic Obstructive Pulmonary Disease COPD (study 201314)

Published: 12-05-2014
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Primary: efficacy and safety of the addition of UMEC 62.5mcg once daily to ICS/LABA therapy, compared with placebo over 12 weeks in subjects with COPD.Secondary: effect of the addition of UMEC to ICS/LABA therapy on COPD-related health status...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON41117

Source
ToetsingOnline

Brief title
study 201314

Condition

- Respiratory disorders NEC

Synonym
COPD; chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: COPD, placebo, UMEC, umeclidinium

Outcome measures

Primary outcome

Trough FEV1 on day 85, Incidence of adverse events.

Secondary outcome

Main: Weighted mean 0-6 hour FEV1 obtained post-dose on Treatment Day 84.

Study description

Background summary

COPD is a major cause of poor health, poor quality of life and is resulting in millions of deaths annually worldwide.
The cornerstone of treatment are longacting B2-agonists (LABA) and inhaled corticosteroids ICS). Salbutamol is used in case of dyspnea. In case of insufficient treatment effect, a longacting muscarinic antagonist (LAMA) is added.
Umeclidinium bromide (UMEC) is a LAMA (dry powder formulation) that has recently been registered in the EU for the treatment of COPD under the name Incruse.
In this study in subjects with COPD the efficacy and safety of UMEC is investigated when added to a LABA and an ICS.

Study objective

Primary: efficacy and safety of the addition of UMEC 62.5mcg once daily to ICS/LABA therapy, compared with placebo over 12 weeks in subjects with COPD.
Secondary: effect of the addition of UMEC to ICS/LABA therapy on COPD-related

health status assessments over 12 weeks in subjects with COPD.

Study design

Multi-center, Randomized Double-blind Parallel Group, Placebo-Controlled Double-Blind phase IV Trial.
Randomization (1:1) to
* UMEC 62,5 mcg once daily.
* Placebo once daily.
Dry powder formulation; in addition to standard treatment with a longacting B2-agonist and an inhaled corticosteroid (twice daily).
Treatment duration 13 weeks.
Study duration approx. 15 weeks.
Approx. 230 patients.

Intervention

Treatment with UMEC or placebo.

Study burden and risks

Risk: adverse events of study treatment.
Burden: 8 study visits plus one final phone call. Duration 1-6h.
Physical examination, pregnancy test, questionnaires (2) 3 times.
Pulmonary function tests: plus reversibility once; single time point 3 visits; multiple time points (6 tests, predose plus up to 6 h post dose) 3 visits.
ECG once.
Paper diary for medical problems plus therapy, use of study medication, other COPD medication, rescue medication.
Optional pharmacogenetic testing (saliva).

Contacts

Public
GlaxoSmithKline

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* 40 years of age or above.
* An established clinical history of COPD in accordance with the definition by the ATS/ERS.
* Current or former cigarette smokers with a history of cigarette smoking of *10 pack-years (see protocol page 26 for details).
* Pre and post-salbutamol FEV1/FVC ratio of <0.70 and post-salbutamol FEV1 of *70% of predicted.
* Must be on the dose and frequency of one of the ICS/LABA combinations approved for COPD and for the study at least 30 days prior screening (see protocol page 26-27 for details).
* Score of *2 on the mMRC.
* Females of childbearing potential: adequate method of contraception. See protocol page 26 for details.

Exclusion criteria

* Hospitalization for COPD or pneumonia within 12 weeks prior to Visit 1.
* Lower respiratory tract infection that required the use of antibiotics within 6 weeks prior to Visit 1.
* Unstable or life threatening cardiac disease. See protocol page 27-28 for details.
* Defined prior therapies. See protocol page 28-29 for details.
* Pregnancy or breastfeeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2014
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Incruse
Generic name:	umeclidinium bromide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-05-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-06-2014
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2014-000611-14-NL
CCMO	NL49073.060.14