A randomised, double-blind, parallel group study to assess the efficacy and safety of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination (2.5 µg / 5 µg; 5 µg / 5 µg) (delivered by the RESPIMAT) compared with the individual components (2.5 µg and 5 µg tiotropium, 5 µg olodaterol) (delivered by the RESPIMAT) in patients with Chronic Obstructive Pulmonary Disease (COPD) [TOnadoTM 1]

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The objective of this study is to assess the efficacy and safety of 52 weeks once daily treatment with orally inhaled tiotropium plus olodaterol fixed dose combination compared with the individual components tiotropium and olodaterol (delivered by...

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

Summary

ID

NL-OMON35802

Source
ToetsingOnline

Brief title
Efficacy and safety tiotropium plus olodaterol

Condition

- Respiratory disorders NEC

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: COPD, efficacy, safety, tiotropium/olodaterol

Outcome measures

Primary outcome

FEV1 AUC 0-3h response

Trough FEV1 response

TDI (in combination with the data of the sister study 1237.6 (not performed in

the Netherlands)

Protocol page 40.

Secondary outcome

FVC AUC 0-3h response (L)

Though FVC response (L)

FEV AUC 0-12hr response (L) (substudy patients with12-hr lungfuction

assessments)

FVC AUC 0-12h response (L) (substudy patients with12-hr lungfuction

assessments)

FEV1 peak 0-3h response (L)

FVC peak 0-3h response (L)

FEV1 response (L) at 5, 15 en 30 minutes and at 1, 2 and 3 hours post

inhalation of study medication

FVC response (L) at 5, 15 en 30 minutes and at 1, 2 and 3 hours post

inhalation of studiemedication

Study description

Background summary

The COPD treatment guidelines advise treatment with bronchodilators with different mechanisms of action. Short acting anticholinergics and beta2-agonists in fixed dose combinations have shown to be effective and safe and are user-friendly to patients. Once daily fixed dose combinations of long-acting anticholinergics and beta2-agonists are not yet available. Tiotropium bromide is a registered once daily long-acting anticholinergic for the treatment of COPD and will be combined with a once daily long-acting beta2-agonist, olodaterol, in this study. Olodaterol is being developed for the treatment of COPD. Is is expected that the combination of these two once daily bronchodilators with different mechanisms of action will provide an optimal long term bronchodilation and is user-friendly.

Study objective

The objective of this study is to assess the efficacy and safety of 52 weeks once daily treatment with orally inhaled tiotropium plus olodaterol fixed dose combination compared with the individual components tiotropium and olodaterol (delivered by the Respimat® Inhaler) in patients with Chronic Obstructive Pulmonary Disease (COPD).

Study design

This is a 52-week multi-centre, multinational, randomised, double-blind,

parallel-group study.

Intervention

Once daily inhalation of study medication with the Respimat® Inhaler (1:1:1:1:1) randomisation to one of the following groups:
- tiotropium plus olodaterol (FDC) 2,5 mcg / 5 mcg) inhalation solution
- titropium plus olodaterol (FDC 5 mcg / 5 mcg) inhalation solution
- olodaterol (5 mcg) inhalation solution
- tiotropium 2,5 mcg inhalation solution
- tiotropium 5 mcg inhalation solution

Twice daily peak flow measurements through the Asthma Monitor 3 (AM3) deivce and documentation of use of rescue medicaiton and study medication.
Restrictions prior to the lung function assessments (See protocol page 38/39).

Study burden and risks

At visits 2, 5, 7 and 10 (week 0, 12, 24 and 52) 3-hr (post-inhalation of study medication) lung function assessments are performed. These visits will take about 5 hours. The patients will receive a compensation for these visits.
During their participation, patients are asked to perform twice daily peak flow assessments with their AM3 monitor and to register the use of rescue medication and study medication.

All patients will receive active medication. Inhalation steroids (except combination preparations with LABAs and SABAs) are both prior and during the study allowed provided that the dosage is stable during 6 weeks prior to the start of the study.
During the screening period patients will receive Ventolin as rescue medication. Besides this, patients who have to wash out tiotropium prior to randomisation are allowed to use atrovent. See for complete overview protocol page 35-37.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with COPD with specific spirometric criteria(FEV1 < 80% of predicted normal and post-bronchodilator FEV1/FVC < 70% bij visite 1)
2. current or ex-smokers with smoking history of more than 10 pack years
3. male or female patients, 40 years of age or older
See protocol page 22

Exclusion criteria

1. Other significant disease other than COPD
2. Clinically relevant abnormal baseline lab values
3. History of Asthma
See protocol page 22/23

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2011
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	olodaterol
Product type:	Medicine
Brand name:	spiriva
Generic name:	tiotropium bromide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-06-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	29-07-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	23-08-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	21-02-2013
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
EudraCT	EUCTR2009-010668-40-NL
CCMO	NL35859.060.11
Other	wordt geregistreerd op clinicaltrial.gov nummer wordt pas na indiening verkregen