A randomized, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 Âµg and 5 Âµg Tiotropium Inhalation Solution delivered by the RespimatÂ® Inhaler with Tiotropium inhalation capsules 18 Âµg delivered by the HandiHalerÂ®.

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To compare the efficacy and safety of 2.5 µg and 5 µg Tiotropium Inhalation Solution delivered by the Respimat® Inhaler with Tiotropium inhalation capsules 18 µg delivered by the HandiHaler®.

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

Summary

ID

NL-OMON36382

Source
ToetsingOnline

Brief title
Tiotropium Safety and Performance In RESPIMAT (TIOSPIR)

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: Sponsor - boehringer ingelheim bv

Intervention

Keyword: efficacy, Respimat®, safety, tiotropium

Outcome measures

Primary outcome

Primary endpoints:

- Time to death (all-cause mortality)

- Time to first COPD exacerbation

Secondary outcome

Secondary endpoints:

- Number of COPD exacerbations

- Time to first hospitalisation due to COPD exacerbation

- Number of hospitalisations due to COPD exacerbations

- Time to first major adverse cardiovascular event

Study description

Background summary

Direct comparison studies of the tiotropium HandiHaler® 18 µg and Respimat® 5 µg formulations have been limited to 4-week crossover studies. Therefore, prospective data from a trial of adequate size and duration is required to

establish that compared to tiotropium HandiHaler®, tiotropium Respimat® will have (a) similar effects on safety and (b) similar or superior effects on exacerbations.

Study objective

To compare the efficacy and safety of 2.5 µg and 5 µg Tiotropium Inhalation Solution delivered by the Respimat® Inhaler with Tiotropium inhalation capsules 18 µg delivered by the HandiHaler®.

Study design

A randomised, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial

Intervention

Eligible patients are assigned to one of the three double-blind treatments at Visit 1 (2,5 mcg or 5 mcg tiotropium inhalation solution, administered with the Respimat® Inhaler, or tiotropium inhalation capsules 18 mcg, administered via the HandiHaler®. The treatment for each patient is determined by random assignment.

Study burden and risks

Patients are requested to visit the clinic about every 3 months over a maximum period of 3 years.
Visit 2: physical ex (basal), ECG, vital signs, pulmonary function testing (FVC/FEV1) only if there are no results available of a PFT performed < 6 months ago; prenancy test (if applicable, visit 1 and end of treatment visit), explanation about study medication inhalation (all clinic visits). Patients are requested to document all changes to (COPD) medication and new or changed symptoms at home in a reminder card.

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.All patients must sign an informed consent consistent with International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines prior to participation in the trial, which includes medication washout and restrictions.
2.Male or female patients 40 years of age or older.
3.Patients must be current or ex-smokers with a smoking history of >=10 pack-years.
4.All patients must have a diagnosis of COPD (according to definition in protocol page 26)
5.Patients must be able to inhale from the HandiHaler® and the Respimat® devices.

Exclusion criteria

1.Significant diseases other than COPD. (see protocl for definitions)
2.Patients with a recent history (i.e., six months or less) of myocardial infarction.
3.Patients with any unstable or life-threatening cardiac arrhythmia requiring intervention or change in drug therapy during the last year.
4.Hospitalisation for cardiac failure (New York Heart Association (NYHA) Class III or IV) during the past year.
5. A respiratory infection or exacerbation of COPD in the four weeks prior to screening.
6. Patients with a history of asthma, cystic fibrosis, bronchiectasis, interstitial lung disease, or pulmonary thromboembolic disease
7. Use of systemic corticosteroid medication at unstable doses (i.e., less than six weeks on stable dose) or at doses in excess of the equivalent of 10 milligrams (mg) prednisolone per day

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):	30-07-2010
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Spiriva
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-04-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-06-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2010
Application type:	Amendment
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)

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	EUCTR2009-015713-51-NL
CCMO	NL31791.060.10