Randomized, double-blind, double-dummy, active-controlled, 4 period complete cross-over study to compare the effect on lung function of 6 weeks once daily treatment with orally inhaled tiotropium+olodaterol fixed dose combination delivered by the Respimat® inhaler vs. 6 weeks twice daily treatment with fluticasone propionate+salmeterol fixed dose combination delivered by the Accuhaler® in patients with Chronic Obstructive Pulmonary Disease (COPD)

Published: 27-06-2013
Last updated: 24-04-2024

Compare if once daily laba/lama treatment with two different dosages shows the same or better result on the 24 hr lungfunction than twice daily treatment of two different dosages with ICS/laba treatment. .

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

Summary

ID

NL-OMON38897

Source
ToetsingOnline

Brief title
ENERGITO

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: 24 hr lungfunction, active controlled, fluticason propionate/salmeterol, tiotropium/olodaterol

Outcome measures

Primary outcome

FEV1 AUC 0-12h (L) response after 6 wks treatment

Secondary outcome

FEV1 AUC 0-24h (L) response after 6 wks treatment

Study description

Background summary

The COPD treatment guidelines advice treatment with bronchodilators with different mechanisms of action. Short acting anticholinergics and beta-2-agonists in fixed dose combinations have shown to be effective and safe and user-friendly for patients. Once daily fixed dose combinations of long-acting anticholinergics for the treatment COPD and will be combined with a once daily long-acting beta-2-agonist, olodaterol. Olodaterol is being developed for the treatment of COPD. It is expected that the combination of

these two once daily bonchodilators withdifferent mechanisms of action will provide an optimal long term bronchodilation and is user-friendly for patients

Study objective

Compare if once daily laba/lama treatment with two different dosages shows the same or better result on the 24 hr lungfunction than twice daily treatment of two different dosages with ICS/laba treatment. .

Study design

randomized, double blind, double dummy, active controlled, complete crossover (4 treatments in 4 periods)

Intervention

Once daily inhalation of study medication with the Respimat inhaler and twice daily inhalation of the comparator with the Accuhaler (Diskus).
4 different treatment periods of 6 weeks each, separated by a washout period of 3 weeks.
Studiemedication: tiotropium + olodaterol 2,5 mcg/5 mcg solution for inhalation, tiotropium + olodaterol 5 mcg/5 mcg solution for inhalation, fluticasone propionate+salmeterol 250 mcg/50 mcg, fluticasone propionate+salmeterol 500 mcg/50 mcg.
Restrictions before randomization and during test days (see E4).

Study burden and risks

visit 2: 2 pre dose lung function tests, 4 post dose lung function tests (up to 3 hr after inhalation) .
Visit 4, 6, 8: 1 pre dose lung function test, 4 post dose lung function tests (up to 3 hr after inhalation) .
visite 3, 5, 7, 9: 1 pre dose (morning dose) lung function test, 15 post dose lung function tests (up to 24 hr after inhalation) .
At these vists the patients stay overnight in the hotel near by the hospital. costs for meals and lodging are paid. Patients will have about 8 hour sleep time at night during these visits.

Visit 1 and 9: ECG , bloodsampling, vital signs (bloodpressure/pulse) and physical examination.
Patients are asked to keep a study diary to write down intake of study medication and rescue medication.
All patients receive Ventolin for rescue medication and Atrovent (at investigators descretion) to use during the washout period if necessary. In each treatment period a safety phone call is made after 3 weeks.

Contacts

Public
Boehringer Ingelheim

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NL
Scientific
Boehringer Ingelheim

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent; Diagnosis of COPD; Male or female patients, 40 years of age or older; Smoking or non-smoker, smoking history of more than 10 pack years; Ability to perform requested procedures (spirometry, diary completion, inhalation of (study)medication.

Exclusion criteria

Significant disease other than COPD ; COPD exacerbation that required treatment with antibiotics, systemic steroids (oral or iv) or hospitalization in the last 3 months before visit 1; Clinically relevant abnormal lab values; clinically relevant cardiovascular diseases; history of asthma; known active tuberculosis; pregnancy/breastfeeding; malignancies for which treatment is given in the past 5 years; history of life-threatening pulmonary obstruction;

History of cystic fibrosis; Clinically evident bronchiectasis; History of significant alcohol or drug abuse; thoracotomy with pulmonary resection; oral or patch ß-adrenergics; Oral corticosteroid medication within 6 weeks prior to Visit 1; use daytime oxygen therapy for more than one hour per day; Pulmonary rehabilitation program in the six weeks prior to the screening visit; Investigational drug within one month or six half lives (whichever is greater) prior to screening visit ;Known hypersensitivity to ß-adrenergic drugs, BAC, EDTA; Pregnant or nursing women

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2013
Enrollment:	66
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet bekend
Generic name:	tiotropiumbromide+olodaterol fixed dose combination
Product type:	Medicine
Brand name:	Seretide
Generic name:	Fluticasone propionate+salmeterol fixed dose combination
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-06-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-12-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2014
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
EudraCT	EUCTR2013-000808-41-NL
CCMO	NL44568.060.13
Other	wordt geregistreeerd op clinical trial.gov en clinical trial.eu, nr. nog niet beschikbaar