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Optimal therapy of chronic obstructive pulmonary disease to prevent exacerbations and improve quality of life

Submission date 17/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2005	**Overall study status** Completed	
Last Edited 25/02/2009	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-63139

Study information

Scientific Title
Optimal therapy of chronic obstructive pulmonary disease to prevent exacerbations and improve quality of life: a randomised, double-blind, placebo-controlled trial

Study objectives
To determine what combination of inhaled medications will most effectively prevent exacerbations of chronic obstructive pulmonary disease (COPD) and optimise disease-specific quality of life in patients with COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ottawa Hospital Research Ethics Board approval was obtained on the 9th April 2003 (amendments: November 4, 2003; January 29, 2004; June 22, 2004).

Study design
Randomised, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
1. Tiotropium 18 µg once a day (OD) plus advair 250 µg two puffs twice a day (BID)
2. Tiotropium 18 µg OD plus salmeterol 25 µg/puffs, two puffs BID
3. Tiotropium 18 µg OD plus placebo inhaler, two puffs BID

Pro re nata (PRN) (as needed) salbutamol use will be allowed throughout the trial period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tiotropium, advair, salmeterol

Primary outcome measure
Proportion of patients who experience a respiratory exacerbation in the three treatment groups within 52 weeks of randomisation.

Secondary outcome measures
1. Changes in quality of life using Chronic Respiratory Disease Questionnaire (CRDQ) and St George's Respiratory Questionnaire (SGRQ) scores
2. Changes in dyspnoea using the baseline Transitional Dyspnoea Indexes (TDI) and Chronic Respiratory Questionnaire (CRQ) dyspnoea domain
3. Number of exacerbations resulting in urgent visits to healthcare provider; or emergency department visits
4. Total number of hospitalisations (all causes)
5. Time to first COPD exacerbation
6. Mean/median number of exacerbations in each treatment group
7. Absolute and relative changes in the morning pre-treatment FEV1 and FVC
8. Use of as-needed salbutamol (puffs/day) - as assessed by patients diary
9. Premature discontinuation of study medication, for reasons of diverse effects or lack of efficacy, as judged by patients physician

Overall study start date
08/10/2003

Completion date
05/01/2006

Eligibility

Key inclusion criteria
1. Patients with moderate or severe COPD who have had at least one exacerbation of COPD in the last 12 months requiring antibiotics and/or oral steroids
2. Patients 35 years and older, either sex
3. Patients must have a history of at least 10-pack years of smoking, and documented chronic airflow obstruction with a forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ratio of less than 0.70, and an FEV1 of less than 65% of predicted

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
432

Key exclusion criteria
1. Patients with a history of atopy, or asthma diagnosed before age 40
2. Patients less than 35 years of age (since patients younger than 35 are unlikely to have COPD)
3. Patients using chronic oral prednisone
4. Patients with known hypersensitivity or intolerance to tiotropum, advair, or salmeterol
5. Patients with a history of chronic congestive heart failure and known severe left ventricular dysfunction (which can mimic and be confused with COPD exacerbation)
6. Patients unable to provide informed consent due to language difficulties or cognitive impairment

Date of first enrolment
08/10/2003

Date of final enrolment
05/01/2006

Locations

Countries of recruitment
Canada

Study participating centre
The Ottawa Hospital
Ottawa, Ontario
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Sponsor information

Organisation
Ottawa Hospital Research Institute (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.ohri.ca/

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63139)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/04/2007		Yes	No