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Preventing viral exacerbation of chronic obstructive pulmonary disease in upper respiratory tract infection: the PREVENT study

Submission date 09/11/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2010	**Overall study status** Completed	
Last Edited 15/02/2018	**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
N/A

Study information

Scientific Title
Preventing viral exacerbation of chronic obstructive pulmonary disease in upper respiratory tract infection: a multinational, double-blinded, randomised controlled trial

Acronym
PREVENT

Study objectives
Background:
Most exacerbations of chronic obstructive pulmonary disease (COPD) are triggered by either bacterial or viral infection or a combination of both. A growing body of evidence implicates viral respiratory tract infection as the predominant risk factor associated with exacerbations of COPD. The synergism of corticosteroid and long-acting β2-agonists in suppressing viral-induced inflammation on airway epithelial cells has been demonstrated in vitro. However, high maintenance dose inhaled steroids is associated with serious adverse effects, particularly pneumonia, in patients with COPD. In asthma, a flexible regimen of inhaled corticosteroid and corticosteroid and long-acting β2-agonists (LABA) 'on-demand' in patients on low maintenance dose steroid/LABA significantly reduces steroid exposure while leading to a decrease in exacerbation rate as compared to a fix regimen of high maintenance dose steroid/ corticosteroid and long-acting β2-agonists. The efficacy of intensified combination therapy with inhaled corticosteroid/LABA at the onset of upper respiratory tract infection symptoms in COPD is unknown.

Aims:
1. To explore the role of different viral infections in exacerbations of COPD and its influence on bacterial co-infection, local and systemic inflammation, airway remodelling and systemic repercussions in patients with COPD
2. To evaluate whether intensified combination therapy with inhaled corticosteroids and long-acting β2-agonists at the onset of upper respiratory tract infection symptoms as compared to placebo decreases the incidence of exacerbation of COPD in patients receiving low maintenance dose inhaled corticosteroids/long-acting β2-agonists, thus reducing disease associated morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Basel - approval pending

Study design
Investigator-initiated and driven double blind randomised multinational trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Additionally to the low maintenance dose steroid/LABA therapy (budesonide 200 µg/formoterol 6 µg bid), patients will be randomised to the combination corticosteroid/long-acting β2-agonists ('steroid/LABA group') or to placebo ('placebo group'). Patients in the steroid/LABA group will receive budenoside 400 µg/formoterol 12 µg bid in case of upper respiratory tract infection symptoms for 10 days. Patients randomised to the placebo group will receive inhaled placebo for 10 days. Low maintenance dose steroid/LABA therapy will be left unchanged in both groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number (%) of patients developing exacerbation within 21 days of URTI onset in the group receiving intensified combination therapy with inhaled steroids/LABA and placebo.

Secondary outcome measures
Viral polymerase chain reaction (PCR) positivity during upper respiratory tract infection (URTI), exacerbations and stable periods; positive sputum bacteriology and positive PCR for atypical pathogens during exacerbation and stable periods; symptoms scores and MMRC dyspnea scale; therapy-related side-effects; duration and cumulative dose of steroids and antibiotics; hospital admission for any cause. Endpoints will be assessed 10 days after upper respiratory tract symptoms onset, after 21 days, in case of exacerbation, and in the stable period of the disease (at 6, 12, and 18 months). In a second step, endpoints will be assessed in subgroups of patients according to the COPD severity.

Overall study start date
01/01/2011

Completion date
30/04/2014

Eligibility

Key inclusion criteria

1. Aged greater than or equal to 40 years
2. Smoking history greater than or equal to 10 pack-years and moderate to very severe stable COPD (Global Initiative for Chronic Obstructive Lung Disease [GOLD] II - IV without exacerbation for greater than or equal to 4 weeks)
3. History of severe exacerbation in previous year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
About 400 participants

Key exclusion criteria
1. Patients with pulmonary conditions other than COPD as the main respiratory disease
2. Rapid lethal disease
3. Severe immunosuppression
4. Known allergy or intolerance to the study medication
5. Pregnancy

Date of first enrolment
01/01/2011

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Belgium

Italy

Netherlands

Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details
Clinic of Pneumology and Respiratory Cell Research
Petersgraben 4
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Sponsor type
Hospital/treatment centre

Website
http://www.unispital-basel.ch/

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland) - Clinic of Pneumology and Respiratory Cell Research

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	01/05/2018		Yes	No