

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/12/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/02/2018	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 β 2-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 long-acting β 2-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 fixed regimen of high maintenance dose steroid/ corticosteroid and long-acting β 2-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 β 2-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 β 2-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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Additionally to the low maintenance dose steroid/LABA therapy (budesonide 200 μ g/formoterol 6 μ g bid), patients will be randomised to the combination corticosteroid/long-acting β 2-agonists ('steroid/LABA group') or to placebo ('placebo group'). Patients in the steroid/LABA group will

receive budesonide 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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