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Efficacy and tolerability of EPs® 7630 in patients with chronic obstructive pulmonary disease (COPD)

Submission date 26/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/05/2009	**Overall study status** Completed	
Last Edited 02/10/2013	**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

Protocol serial number
701006.01.001

Study information

Scientific Title
Phase III study to prove the efficacy and tolerability of EPs® 7630 in patients aged greater than or equal to 18 years old with chronic obstructive pulmonary disease (COPD)

Study objectives
To determine the effect of EPs® 7630 (a liquid herbal drug preparation from the roots of Pelargonium sidoides) on time to occurrence of the first acute exacerbation in patients with chronic obstructive pulmonary disease (COPD) compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee and the State Pharmacological Centre of Ukraine approved on the 26/10/2005 (ref: 5.12-408/KE)

Primary study design
Interventional

Study design
Phase III multicentre double-blind randomised placebo-controlled trial

Study type(s)
Treatment

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

Interventions
EPs® 7630 solution or placebo 30 drops three times a day orally for 24 weeks as an add-on therapy to a standardised baseline treatment for COPD.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
EPs® 7630 (Pelargonium sidoides extract)

Primary outcome(s)
Time to occurrence of first acute exacerbation during the treatment period of 24 weeks.

Key secondary outcome(s)
1. Number of acute exacerbations during the treatment period of 24 weeks
2. Duration of an acute exacerbation until it has subsided
3. Measurement of FEV1, forced vital capacity (FVC), and FEV1/FVC ratio every 4 weeks for 24 weeks
4. Measurement of FEV1, FVC, and FEV1/FVC ratio at begin and end of an acute exacerbation
5. Health status of the patients using the health-related Quality of Life questionnaire (EQ-5D) and St. George's Respiratory Questionnaire (SGRQ), assessed at baseline and every 4 weeks for 24 weeks
6. Treatment outcome using the Integrative Medicine Outcomes Scale (IMOS), assessed every 4

weeks for 24 weeks
7. Patient's satisfaction with treatment using the Integrative Medicine Patient Satisfaction Scale (IMPSS), assessed every 4 weeks for 24 weeks
8. Duration of limitation of physical activity during an acute exacerbation
9. Duration of patient's inability to work during an acute exacerbation
10. Consumption of paracetamol, Zedex, salmeterol, Berodual N, and budesonide by inhalation during the treatment period of 24 weeks
11. Consumption of salmeterol, budesonide, oral prednisone, Berodual N, and augmentinum (or ofloxacin) during an acute exacerbation
12. Pack year calculation and changes of smoking habits, assessed at baseline and every 4 weeks for 24 weeks
13. Adverse events surveillance: total duration of follow-up: 24 weeks
14. Laboratory values, assessed at baseline and every 4 weeks for 24 weeks

Completion date
16/06/2008

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 18 years, both males and females
2. Written informed consent
3. History of chronic bronchitis (characterised by cough and sputum production on most days for a minimum of 3 months per year for at least 2 consecutive years)
4. Patients with stable COPD (no changes in volume or appearance of sputum or level of dyspnoea in the previous 4 weeks)
5. History of acute exacerbation greater than or equal to 3 times in the prior 12 months
6. Forced expiratory volume during one second (FEV1) less than 80% and greater than or equal to 30% predicted (COPD stage II, III)
7. Improvement of FEV1 during the initial FEV1 reversibility test is less than or equal to 0.3 l after two puffs of Berodual N

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients suffering from cardiac diseases, pneumonia, active pulmonary tuberculosis, cystic fibrosis, bronchiectasis, lung cancer, acquired immune deficiency sydrome (AIDS)

2. Patients with asthma bronchiale
3. COPD patients in stage IV (FEV1 less than 30% predicted)
4. Patients with infiltrates or other abnormalities of the lungs indicating an active pathological process on chest x-ray
5. Patients with acute exacerbation within the last 4 weeks
6. Known concomitant bacterial infection or infections of respiratory tract
7. Concomitant medication with beta-blockers, angiotensin converting enzyme (ACE)-inhibitors, regular inhalative glucocorticoids (except in COPD patients stage III), oral glucocorticoids (except during an acute exacerbation), anticholinergics (except ipratropium bromide in Berodual N), beta-2-agonists other than salmeterol or fenoterol in Berodual N, analgetics other than paracetamol, mucolytics and antitussives other than Zedex, immunomodulators (e.g. bacterial vaccines), or coumarin-derivatives
8. Treatment with antibiotics, beta-blockers, ACE-inhibitors, anticholinergics (except ipratropium bromide in Berodual N), inhalative glucocorticoids (except in COPD patients stage III) or oral glucocorticoids within the last 4 weeks prior study inclusion
9. Known alcohol or drug abuse
10. Patients with tendency to bleed
11. Severe heart, renal or liver diseases and/or immunosuppression
12. Gastrointestinal disorders
13. Patients with known or supposed hypersensitivity against EPs® 7630
14. Females of child-bearing potential with no adequate contraception
15. Pregnancy or lactation
16. Patients participating in another clinical trial at the same time or have taken part in a clinical trial during the last 3 months before inclusion into this study
17. Irresponsible patients or those unable to understand nature, meaning and consequences of the trial

Date of first enrolment
13/03/2006

Date of final enrolment
16/06/2008

Locations

Countries of recruitment
Ukraine

Study participating centre
Faculty Therapy No. 2
Kiev
Ukraine
01103

Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr Willmar Schwabe GmbH & Co. KG (Germany)

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	01/05/2013		Yes	No