ISRCTN19646069 https://doi.org/10.1186/ISRCTN19646069

Short versus conventional term glucocorticoid therapy in acute exacerbations of chronic obstructive pulmonary disease: the REDUCE trial

Submission date 21/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 23/05/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jonas Rutishauser

Contact details
University Hospital Basel
Department of Internal Medicine
Petersgraben 4
Basel
Switzerland
4031
+41 (0)61 265 4665
j.rutishauser@unibas.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
REDUCE

Study objectives
Our hypothesis is that in exacerbated Chronic Obstructive Pulmonary Disease (COPD), a 5-day glucocorticoid treatment course will result in the same clinical outcome as a standard 14-day regimen

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial was approved by the Ethics Committee of Basel (EKBB), reference number 167/0, the amendment dates from 16/01/2006. This trial was also approved by the Swiss Federal Authority (Swiss Agency for Therapeutic Products [SWISSMEDIC]) on 23/01/2006, protocol reference number: 2006DR4021.

Study design
Prospective, randomized, double-blind, placebo-controlled, non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD)

Interventions
Comparison of 5-day to 14-day systemic glucocorticoid
therapy

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to next COPD exacerbation

Secondary outcome measures
1. Cumulative steroid dose
2. Time to open-label standard-dose glucocorticoid therapy during the index exacerbation
3. Need for invasive or non-invasive mechanical ventilation
4. Change in FEV1
5. Clinical outcome at discharge and during follow-up as assessed by a standardized worksheet and questionnaire. Dyspnoea will be assessed according to the ATS consensus statement.
6. Duration of hospital stay
7. Death from any cause
8. Steroid-associated side-effects and complications:
a. Development or exacerbation of hyperglycemia (defined as fasting plasma glucose ≥5.6mmol /l or random plasma glucose ≥7.8 mmol/l or rise by ≥20% in daily doses of insulin or oral anti-diabetic drugs or initiation of one or more anti-diabetic therapeutic principle) respectively
b. Development or worsening of hypertension (defined as blood pressure ≥140 mmHg systolic and/or ≥90 mmHg diastolic; or the addition of one or more antihypertensive drugs to previous treatment regimens
c. Suppression of the adrenal function at study entry and during follow-up as assessed with the low dose (1 ug) adrenocorticotropic hormone (ACTH) stimulation test
d. Secondary infections
e. Effects on bone turnover, assessed by specific biochemical markers (endpoint updated in April 2006)
f. Other potential steroid-related adverse events (e.g. gastrointestinal bleeding or psychiatric disease)

Overall study start date
27/02/2006

Completion date
27/02/2009

Eligibility

Key inclusion criteria
1. Clinical diagnosis of exacerbated COPD, defined by the presence of at least two of the following:
a. Change in baseline dyspnoea
b. Cough
c. Sputum (levels I III according to American Thoracic Society [ATS] or European Respiratory Society [ERS] criteria)
2. Age ≥40 years
3. History of ≥20 pack-years of cigarette smoking

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
390

Key exclusion criteria
1. Inability to give informed consent
2. Diagnosis of asthma
3. Forced expiratory volume in one second (FEV1) or Forced Vital Capacities (FVC) (Tiffenau) >70% (bedside post-bronchodilator)
4. Radiological diagnosis of pneumonia
5. Coexisting disease making survival of >6 months unlikely
6. Pregnancy or lactation (pregnancy test mandatory for pre-menopausal women)

Date of first enrolment
27/02/2006

Date of final enrolment
27/02/2009

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel, Department of Internal Medicine (Switzerland)

Sponsor details
c/o Prof. J. Schifferli (Head)
Petersgraben 4

Basel
Switzerland
4031 Basel

Sponsor type
University/education

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

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
University/education

Funder Name
In-house grant from the Department of Medicine, University Hospital Basel, Switzerland

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	05/06/2013		Yes	No