

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2013	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

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Time to next COPD exacerbation

Key secondary outcome(s))

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 ≥ 5.6 mmol/l or random plasma glucose ≥ 7.8 mmol/l or rise by $\geq 20\%$ 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) adrenocorticotrophic 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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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