

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

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|--|---|---|
| <b>Submission date</b><br>21/02/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>08/03/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>23/05/2013       | <b>Condition category</b><br>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

**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  $\geq 5.6$  mmol/l or random plasma glucose  $\geq 7.8$  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  $\geq 140$  mmHg systolic and/or  $\geq 90$  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)

**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  $\geq 40$  years
3. History of  $\geq 20$  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

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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 05/06/2013   |            | Yes            | No              |