

EXCALIBUR

Prompt Sheet for Clinicians

Adults, 40 years or over, presenting in Primary Care with suspected acute exacerbation of COPD (AECOPD) can potentially be included; a delayed prescription is encouraged but you can decide on immediate, delayed or no prescription approach.

In general, the trial medication has a low level of side effects.

Main safety concerns:

- Pregnancy & lactation (no data to confirm safety) exclude women who are pregnant or breastfeeding.
- Women at risk of pregnancy must be on adequate contraception.
- Severe liver or kidney disease (no data to confirm safety) exclude patients with severe hepatic and renal diseases (Chronic Kidney Disease Stage 4 or 5).

Objectives of the study

• To evaluate the feasibility of a trial of herbal medicine in acute exacerbation of COPD.

Inclusion Criteria

- Has a current acute exacerbation of COPD with <u>at least one</u> of the following:
 - Increased sputum purulence
 - $\circ \ \ \, \text{Increased sputum volume}$
 - Increased breathlessness
- The current acute exacerbation has lasted for at least 24 hours and no longer than 21 days
- The responsible clinician is considering use of antibiotics for the acute exacerbation
- Diagnosis of COPD in clinical record
- Age 40 years or more
- Able to provide informed consent
- Able to provide the primary outcome data at 2 and 4 weeks within the expected windows

Exclusion Criteria

- The responsible clinician feels urgent referral to hospital is necessary
- Severe illness (e.g. suspected pneumonia or pulmonary embolism or lung cancer; necessity for emergency admission to hospital)
- Patient has a primary diagnosis of bronchiectasis, lung cancer or other active chronic respiratory disease
- Currently on or has previously had antibiotics or corticosteroids for this AECOPD
- Patient is on a maintenance dose of antibiotics for treatment of COPD
- Known or suspected pregnancy
- Women of childbearing potential who are at risk of pregnancy and not using an effective form of contraception
- Currently breast-feeding
- Chronic kidney disease stage 4 or 5
- Severe liver disease
- Cannot read or understand the study materials
- Previously recruited into this "EXCALIBUR" trial
- Previously been recruited into another drug trial within the last 6 weeks



Southampton