ISRCTN49790596 https://doi.org/10.1186/ISRCTN49790596

# Inhaled Promixin® in the treatment of non-cystic fibrosis bronchiectasis

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 20/10/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 31/10/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 09/09/2014 | Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Charles Haworth

**Contact details**
Consultant in Respiratory Medicine
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## Additional identifiers

**Clinical Trials Information System (CTIS)**
2008-005045-34

**Protocol serial number**
PPCTP/001

## Study information

**Scientific Title**
A double-blind, vehicle-controlled, multi-centre, clinical study to investigate the efficacy and safety of up to 6 months of therapy with inhaled Promixin® in the treatment of patients with

non-cystic fibrosis bronchiectasis infected with Pseudomonas aeruginosa susceptible to Promixin®

## Acronym
PROMIS

## Study objectives
Promixin® (colistimethate sodium) is currently approved for use in the management of patients with cystic fibrosis (CF) bronchiectasis who have pseudomonal lung infections, but not for use in patients with non-CF bronchiectasis who have pseudomonal lung infections. The infective agent is the same in both cases and it could be expected that Promixin® will provide benefit in patients with non-CF bronchiectasis as well as patients with CF bronchiectasis.

The purpose of this study is to determine if the use of inhaled colistimethate sodium (Promixin®) increases the time, compared to vehicle, from starting treatment with the investigational medicinal product (IMP) until the patients experience an infective pulmonary exacerbation, in patients with non-CF bronchiectasis infected with Pseudomonas aeruginosa (P. aeruginosa) susceptible to Promixin®. Treatment will be for up to 6 months and the safety profile of inhaled Promixin® therapy will be evaluated over this period.

On 28/09/2011 the following changes were made to the trial record:
1. The anticipated end date was changed from 26/08/2010 to 31/01/2012.
2. The Russian Federation and Ukraine have been added to the countires of recruitment.
3. The target number of participants was changed from 260 to 144; recruitment is now complete.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Submitted to London Research Ethics Committee Northwick Park Hospital for the meeting on 29 /10/2008 (ref: 08/H0718/71)

## Study design
Multi-centre double-blind parallel-group vehicle-controlled randomised study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Non-cystic fibrosis bronchiectasis; patients with proven Pseudomonas aeruginosa pulmonary infections

## Interventions
Investigational medicinal product:
Inhaled Promixin® (colistimethate sodium) at a concentration of 1 million international units per mL (300 µL dose via an I-neb™ system) administered twice a day for up to 6 months.

Control:
Vehicle, 0.45% saline(300 µL dose via an I-neb™ system) administered twice a day for up to 6 months.

Joint/scientific contact details:
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### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Promixin® (colistimethate sodium)

### Primary outcome(s)
The time (in days) from baseline/visit 2 (first dose) for each individual patient, until he/she experiences an exacerbation.

### Key secondary outcome(s))
1. Number of adverse events and serious adverse events, measured at end of the patients' involvement in the study
2. Changes in sputum mass from baseline to week 4
3. Changes in sputum flora, measured over the course of the study, samples collected at weeks 4, 12 and at the end of the patients' involvement in the study
4. Improvement in quality of life as assessed by Saint George's Respiratory Questionnaire (SGRQ) and compliance with treatment, measured at week 12 and at the end of the patients' involvement in the study
5. Changes in forced expiratory volume in one second (FEV1), measured at the end of the patients' involvement in the study and at the first dose

### Completion date
31/01/2012

## Eligibility

### Key inclusion criteria
1. Patients of either gender, over 18 years of age
2. Non-CF bronchiectasis
3. Are known to have grown P. aeruginosa from their sputum at least twice in the previous 12 months
4. Have experienced and completed treatment for an exacerbation of bronchiectasis within 21 days of screening

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. CF bronchiectasis
2. Confirmed recent allergic bronchopulmonary aspergillosis
3. Immune suppression, hypogammaglobulinaemia, inflammatory bowel disease, primary ciliary dyskinesia or myloproliferative disease
4. Bronchoreactivity
5. Have used colistimethate sodium in the past, or are taking hypertonic saline, high doses of steroid or anti-tumour necrotising factor alpha (anti-TNFa)
6. Have recently started azithromycin
7. Female patients who are pregnant or nursing

### Date of first enrolment
26/01/2009

### Date of final enrolment
31/01/2012

## Locations

### Countries of recruitment
United Kingdom

England

Russian Federation

Ukraine

### Study participating centre
### Consultant in Respiratory Medicine
Cambridge
United Kingdom
CB23 3RE

# Sponsor information

**Organisation**
Profile Pharma Ltd (UK)

**ROR**
https://ror.org/00222m642

# Funder(s)

**Funder type**
Industry

**Funder Name**
Profile Pharma Ltd (UK) (ref: PPCTP/001)

# 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 | 15/04/2014 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |