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

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

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
2008-005045-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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:
Diana Bilton MD FRCP
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Intervention Type
Drug

Phase
Not Applicable

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

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

Secondary outcome measures
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

Overall study start date

26/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

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

England

Russian Federation

Ukraine

United Kingdom

Study participating centre
Consultant in Respiratory Medicine
Cambridge
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CB23 3RE

Sponsor information

Organisation
Profile Pharma Ltd (UK)

Sponsor details
Bicentennial Building
Southern Gate
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Sponsor type
Industry

Website
http://www.profilepharma.com/

ROR
https://ror.org/00222m642

Funder(s)

Funder type
Industry

Funder Name

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