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# Double Blind Randomised Placebo Controlled Trial of Oral Co-trimoxazole in Pulmonary Fibrosis

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| **Submission date**<br>25/08/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>09/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>05/07/2018 | **Condition category**<br>Circulatory System | |

**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**
UK study number for local regional ethical committee (LREC) 64/99

# Study information

### Scientific Title
Double Blind Randomised Placebo Controlled Trial of Oral Co-trimoxazole in Pulmonary Fibrosis

### Acronym
Septrin and CFA

### Study objectives
Oral Co-trimoxazole improves exercise capacity in patients with pulmonary fibrosis

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled 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
Idiopathic pulmonary fibrosis (UIP/NSIP/Mixed)

### Interventions
Investigations prior to selection and randomisation:
All selected patients underwent baseline investigations before entry. This included:
1. Arterial gases at rest (on air)
2. Pulmonary function tests (laboratory measurement of TLC, DLCO)
3. St Georges Hospital respiratory questionnaire (SGHRQ), and MRC 5 Point Dyspnoea Score
4. Two shuttle-walking tests (2 weeks apart) demonstrating oxygen desaturation below 90% (either during or upon cessation of exercise)
5. An echocardiogram and ECG
6. Routine bloods tests including serum samples for cytokine measurements
7. Sputum samples for pneumocystis silver stain at request of Ethics Committee

Randomisation:
Patients were randomly allocated to active or placebo treatments by our clinical trials pharmacist, using computer generated random numbers. This assigned patients to study treatment groups, with a patient number. The study was conducted double blind. To preserve the double blind status of the trial, medication was issued by the pharmacist; using identical placebo tablets and labelling to ensure all treatment packs were identical.

Drug Treatment:
Co-trimoxazole or identical placebo (480 mg) tablets were supplied with dosage according to body-weight. Patients up to 70 kg received 960 mg bd, those above 70 kg, took 1440 mg (3 x 480 mg) bd. Folic acid 5 mg was given 3 times a week (minimum dose) to protect the bone marrow. Ranitidine 150 mg bd was supplied but optional for any indigestion. Patients on oral daily prednisolone had no adjustments to their prednisolone dose throughout the double blind study, except that permitted during a viral illness.

Assessment during Study:
On entry to the study all patients made visits for the following assessments every 2 weeks:
1. Body-weight
2. Resting respiratory rate and chest auscultation
3. FVC
4. Oxygen saturations at rest and during shuttle walking test and recovery recorded by Pulsox 3i wrist watch Minolta range
5. MRC-5 Point Dyspnoea Score
6. Compliance with treatment/side effects/study withdrawal and deaths were assessed and recorded
7. Blood tests (FBC, U & E, LFTs, ESR and CRP)
At 3 months all patients had arterial gases, full pulmonary function tests, serum cytokines and SGHRQ, repeated. Six weeks of pulmonary rehabilitation (rehab) was then commenced. Two weeks post rehabilitation final assessments were made before decoding. These assessments were identical to the regular 2 week assessments during the study.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Co-trimoxazole

## Primary outcome measure
Exercise capacity (shuttle walking test) with area under the curve oxygen desaturation

## Secondary outcome measures
1. Respiratory function tests (FVC, TLC, DLCO)
2. Arterial oxygen measurements
3. Quality of life data
4. Benefit of pulmonary rehabilitation
Twenty patients were selected.

## Overall study start date

21/02/2000

### Completion date
01/02/2004

## Eligibility

### Key inclusion criteria
1. Male or female below 85 years old
2. Demonstrated breathlessness with oxygen desaturation below 90% on two baseline shuttle walking tests (SWT)
3. Physical examination, HRCT scan and pulmonary function test results compatible with IPF (with or without histological diagnosis)
4. New diagnosis of IPF without treatment or previous diagnosis on regular daily prednisolone
5. Symptoms of exertional dyspnoea affecting life quality
6. Normal glucose 6-phosphate dehydrogenase levels to avoid drug induced haemolysis. Normal vitamin B12 levels

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
20

### Key exclusion criteria
1. Recognised secondary causes of pulmonary fibrosis
2. Co-trimoxazole allergy or severe upper GI symptoms
3. Abnormal liver function tests or concurrent drug treatments that disturb liver function including azathioprine
4. Inability to perform the shuttle test due to musculoskeletal or cardiac causes

### Date of first enrolment
21/02/2000

### Date of final enrolment
01/02/2004

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**St Helier Hospital**
Carshalton
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# Sponsor information

**Organisation**
The Peel Trust Fund (UK)

**Sponsor details**
Sceptre Court
40 Tower Hill
Gloucester
United Kingdom
GL1 3NN

**Sponsor type**
Charity

**ROR**
https://ror.org/05ag50972

# Funder(s)

**Funder type**
Charity

**Funder Name**
Part funded by The Peel Trust Fund for funding of placebo and Co-trimoxazole drugs only

# 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 | 01/05/2008 | | Yes | No |