An open, randomised trial to compare desensitisation with rechallenge when restarting co-trimoxazole as prophylaxis against pneumocystis carinii pneumonia (PCP) in patients with Human Immunodeficiency Virus (HIV) infection and a history of mild to moderate cutaneous and/or febrile reactions to co-trimoxazole

Submission date	Recruitment status	Prospectively registered
03/10/2000	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/10/2000	Completed	Results
Last Edited	Condition category	Individual participant data
05/11/2012	Infections and Infestations	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Sheena McCormack

#### Contact details

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# Additional identifiers

## **EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers G9703068

# Study information

#### Scientific Title

### **Acronym**

The COTOX trial

### **Study objectives**

To determine the best strategy to enable patients with past or current reactions on cotrimoxazole to be able to continue taking co-trimoxazole. (Co-trimoxazole is significantly better than alternative drugs for PCP prophylaxis)

### 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)

**Not Specified** 

### Participant information sheet

# Health condition(s) or problem(s) studied

HIV, Acquired Immunodeficiency Syndrome (AIDS)

#### **Interventions**

Co-trimoxazole/desensitisation/direct rechallenge

#### Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

co-trimoxazole

## Primary outcome measure

Proportion of patients still taking co-trimoxazole four and 24 weeks after trial entry

## Secondary outcome measures

Not provided at time of registration

## Overall study start date

01/04/1998

#### Completion date

01/04/2001

# **Eligibility**

### Key inclusion criteria

- 1. Past or current severe reactions to co-trimoxazole
- 2. Other severe skin conditions
- 3. Creatinine above 250 micromoles/l, Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) above five times local limit
- 4. Haemoglobin below 10.5 g/dl, neutrophils below 0.75, platelets below 50

# Participant type(s)

Patient

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

388

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/04/1998

#### Date of final enrolment

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre MRC Clinical Trials Unit London United Kingdom NW1 2DA

# Sponsor information

# Organisation

Medical Research Council (MRC) (UK)

## Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

### Sponsor type

Research council

#### Website

http://www.mrc.ac.uk

# Funder(s)

## Funder type

Research council

#### **Funder Name**

Medical Research Council (MRC) (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

#### Location

United Kingdom

# **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