

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

03/10/2000

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

03/10/2000

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

05/11/2012

Condition category

Infections and Infestations

Individual participant data

Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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 co-trimoxazole 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/1998

Date of final enrolment

01/04/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration