ISRCTN74775699 https://doi.org/10.1186/ISRCTN74775699

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

Registration date
03/10/2000

Overall study status
Completed

Last Edited
05/11/2012

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
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

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

01/04/2001

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
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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