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Randomised open-label cross over study to investigate patient tolerance of itraconazole liquid when administered either at room temperature or chilled: ambient vs chilled itraconazole study

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 13/02/2018	**Condition category** Infections and Infestations	

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
N0256124185

Study information

Scientific Title
Randomised open-label cross over study to investigate patient tolerance of itraconazole liquid when administered either at room temperature or chilled: ambient vs chilled itraconazole study

Study objectives
Will altering the temperature of prophylactic itraconazole suspension make it more palatable to patients and encourage compliance?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Not specified

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
Fungal infections in immunocompromised patients

Interventions
Clinical trial of ambient versus chilled itraconazole liquid

Intervention Type
Drug

Phase

Not Applicable

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

Primary outcome measure
Service outcome development

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/05/2003

Completion date
30/08/2003

Eligibility

Key inclusion criteria
20 patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
20/05/2003

Date of final enrolment
30/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Free & University College Medical School
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK)

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