

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

Registration date

30/09/2004

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

13/02/2018

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

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