

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

Dr Michael Potter

Contact details

Department of Haematology
The Royal Free & University College Medical School
Pond Street
Hampstead
London
United Kingdom
NW3 2QG

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised open controlled crossover group trial

Study type(s)

Treatment

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(s)

Service outcome development

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/08/2003

Eligibility

Key inclusion criteria

20 patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

The Royal Free & University College Medical School

London

United Kingdom

NW3 2QG

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Royal Free Hampstead NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration