

# 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**

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## 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

## Study design

Randomised open controlled crossover group trial

## Primary study design

Interventional

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes