

# A randomised controlled pilot study in the use of hyperbaric oxygen therapy versus metronidazole in chronic pouchitis

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/07/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Gerald Laden

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0084118523

# Study information

## Scientific Title

A randomised controlled pilot study in the use of hyperbaric oxygen therapy versus metronidazole in chronic pouchitis

## Study objectives

To assess the benefits and effectiveness of hyperbaric oxygenation as a potential new treatment for chronic or refractory pouchitis.

## 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)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Pouchitis

## Interventions

Randomised controlled trial comparing:

1. Hyperbaric oxygen therapy
2. Metronizadole

## Intervention Type

Mixed

## Primary outcome measure

Not provided at time of registration

## Secondary outcome measures

Not provided at time of registration

**Overall study start date**

30/09/2002

**Completion date**

10/12/2005

## Eligibility

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Total number required: 30

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

30/09/2002

**Date of final enrolment**

10/12/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Hyperbaric Medicine Unit

Hull

United Kingdom

HU10 7AZ

## Sponsor information

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

**Funder(s)****Funder type**

Government

**Funder Name**

The North and South Bank Research and Development Consortium (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