

# Porous vs nonporous enucleation implants: a randomised study

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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**  
N0207158225

# Study information

## Scientific Title

Porous vs nonporous enucleation implants: a randomised study

## Study objectives

The aim of this study is to compare patient satisfaction and incidence of complications associated with porous and non-porous enucleation implants.

## 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)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

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

Surgery: Eye

## Interventions

Randomised, prospective study

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

## Primary outcome measure

Patient comfort, satisfaction and complications according to type of orbital implant after enucleation for ocular melanoma.

## Secondary outcome measures

Not provided at time of registration

**Overall study start date**

01/07/2004

**Completion date**

01/07/2014

## Eligibility

**Key inclusion criteria**

Approximately 400 patients will be invited to participate, and it is likely that 300 patients will accept. The patients will almost all be aged 20 or more, with the peak age being 60 years.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

300

**Key exclusion criteria**

1. Previous treatment
2. Evidence of systematic malignancy
3. Inability to complete written questionnaires measuring quality of life
4. Overseas residence beyond the British Isles

**Date of first enrolment**

01/07/2004

**Date of final enrolment**

01/07/2014

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St Paul's Eye Unit**

Liverpool

United Kingdom

L7 8XP

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Government

## Funder Name

Royal Liverpool and Broadgreen University Hospitals Trust

## Funder Name

NHS R&D Support Funding - No External Funding

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2017	22/01/2019	Yes	No