

Porous vs nonporous enucleation implants: a randomised study

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/01/2019	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Bertil Damato

Contact details
St Paul's Eye Unit
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP
+44 (0)151 706 3965
bertil.damato@btinternet.com

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Eye

Interventions

Randomised, prospective study

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

St Paul's Eye Unit

Liverpool

United Kingdom

L7 8XP

Sponsor information**Organisation**

Department of Health

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

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?
Results article	results	01/11/2017	22/01/2019	Yes	No