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Porous vs nonporous enucleation implants: a randomised study

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

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