

A prospective randomised study of the early complication rates of hydroxyapatite versus Medpor orbital implant in the post-enucleation and evisceration socket

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/04/2015	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0547145274

Study information

Scientific Title

A prospective randomised study of the early complication rates of hydroxyapatite versus Medpor orbital implant in the post-enucleation and evisceration socket

Study objectives

To determine in a prospective and randomised manner if hydroxyapatite or Medpor is associated with lower rate of complication in the early post-operative period (ie within 3 months of surgery).

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

Surgery: Orbitant implants

Interventions

Hydroxyapatite versus Medpor

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Rate of complication within the first 3 months post surgery.

Secondary outcome measures

Number of additional unplanned surgical procedures in that period.

Overall study start date

01/10/2003

Completion date

01/10/2005

Eligibility**Key inclusion criteria**

All patients having an eyeball removed and having orbital implants inserted at the same operation.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

80

Key exclusion criteria

Patients who are having implants inserted in a secondary procedure.

Date of first enrolment

01/10/2003

Date of final enrolment

01/10/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 2QQ

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

East Norfolk and Waveney Research Consortium - Norfolk and Norwich University, Hospital /Norwich PCT (UK), NHS R&D Support 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

