ISRCTN55878769 https://doi.org/10.1186/ISRCTN55878769

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	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/04/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A Ang

Contact details
Ophthalmology Department
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

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