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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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
16/04/2015

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Orbitant implants

Interventions
Hydroxyapatite versus Medpor

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Rate of complication within the first 3 months post surgery.

Key secondary outcome(s)
Number of additional unplanned surgical procedures in that period.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration