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Comparative evaluation of efficacy and safety of ophthalmic viscosurgical devices in phacoemulsification

Submission date 18/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2005	**Overall study status** Completed	
Last Edited 19/02/2008	**Condition category** 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
N/A

Study information

Scientific Title

Acronym
Ophthalmic viscosurgical devices

Study objectives
To compare the efficacy and safety of three ophthalmic viscosurgical devices that are routinely used in phacoemulsification.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Senile Cataract

Interventions
Comparing three viscosurgical devices namely Viscoat®, Healon GV® and Healon 5® in performing phacoemulsification.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure

The safety and efficacy of the three viscosurgical devices namely Viscoat®, Healon GV® and Healon 5® in performing phacoemulsification is comparable.

Secondary outcome measures
Viscoat® can result in a mild transient rise in the intraocular pressure.

Overall study start date
05/01/2004

Completion date
27/03/2004

Eligibility

Key inclusion criteria
1. More than 40 years of age
2. Senile cataract
3. Nucleus hardness of grade 3/4
4. Not having any evidence of subluxation or pseudoexfoliation
5. Not having any other associated ocular pathology

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56

Key exclusion criteria
Pre-existing glaucoma and intraoperative events like manual dilatation of pupil, posterior capsular rent and placement of intraocular lens (IOL) in the sulcus

Date of first enrolment
05/01/2004

Date of final enrolment
27/03/2004

Locations

Countries of recruitment
India

Study participating centre
R. P. Centre
New Delhi
India
110029

Sponsor information

Organisation
All India Institute of Medical Sciences (AIIMS) (India)

Sponsor details
R. P. Centre
Ansari Nagar
New Delhi
India
110029

Sponsor type
University/education

ROR
https://ror.org/02dwcqs71

Funder(s)

Funder type
University/education

Funder Name
All India Institute of Medical Sciences (AIIMS) (India)

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	15/07/2005		Yes	No