

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

Submission date 18/06/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/02/2008	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/02dwcqs71>

Funder(s)

Funder type

University/education

Funder Name

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

Results and Publications

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