

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

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|--|---|---|
| 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

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 |