Clinical Trial Details (PDF Generation Date :- Wed, 17 Jan 2018 04:44:34 GMT)

CTRI Number
CTRI/2016/06/007022 [Registered on: 14/06/2016] - Trial Registered Retrospectively

Last Modified On
05/05/2016

Post Graduate Thesis
Yes

Type of Trial
Interventional

Type of Study
Surgical/Anesthesia

Study Design
Randomized, Parallel Group, Multiple Arm Trial

Public Title of Study
A comparative study of different infusion systems and phacoemulsification tips for cataract surgery

Scientific Title of Study
EFFECT OF IOP BASED INFUSION SYSTEM WITH OR WITHOUT BALANCED PHACO TIP ON CUMULATIVE DISSIPATED ENERGY AND ESTIMATED FLUID USAGE IN COMPARISON TO GRAVITY FED INFUSION SYSTEM IN TORSIONAL PHACOEMULSIFICATION

Secondary IDs if Any
Secondary ID
NIL
Identifier
NIL

Details of Principal Investigator
Name
Dr Praveen Kumar Malik
Designation
Professor & Head of the Department
Affiliation
PGIMER & RML Hospital
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Department of Ophthalmology PGIMER & RML Hospital Baba Kharak Singh Marg Central DELHI 110001 India
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Fax
Email
praveenk002@yahoo.com

Details Contact Person (Scientific Query)
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Dr Taru Dewan
Designation
Associate Professor and Senior Eye Specialist
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Phone
9810673180
Fax
Email
taru.dewan@hotmail.com

Details Contact Person (Public Query)
Name
Ekta Sain
Designation
postgraduate student
Affiliation
PGIMER & RML Hospital
Address
Department of Ophthalmology PGIMER & RML Hospital Baba Kharak Singh Marg Central DELHI 110001 India
### Source of Monetary or Material Support

<table>
<thead>
<tr>
<th>Source of Monetary or Material Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGIMER &amp; RML Hospital Baba Kharak Singh Marg NEW DELHI 110001</td>
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### Primary Sponsor

<table>
<thead>
<tr>
<th>Primary Sponsor Details</th>
</tr>
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<tbody>
<tr>
<td>Name: PGIMER RML Hospital</td>
</tr>
<tr>
<td>Address: Department of Ophthalmology, PGIMER &amp; RML Hospital baba kharak singh marg New Delhi</td>
</tr>
<tr>
<td>Type of Sponsor: Research institution and hospital</td>
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### Details of Secondary Sponsor

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIL</td>
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</tbody>
</table>

### Countries of Recruitment

<table>
<thead>
<tr>
<th>List of Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
</tr>
</tbody>
</table>

### Sites of Study

<table>
<thead>
<tr>
<th>Name of Principal Investigator</th>
<th>Name of Site</th>
<th>Site Address</th>
<th>Phone/Fax/Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Praveen Kumar Malik</td>
<td>PGIMER &amp; RML Hospital</td>
<td>Eye Department PGIMER &amp; DR RML Hospital Baba Kharak Singh Marg Central DELHI</td>
<td>9810405681 <a href="mailto:praveenk002@yahoo.com">praveenk002@yahoo.com</a></td>
</tr>
</tbody>
</table>

### Details of Ethics Committee

<table>
<thead>
<tr>
<th>Name of Committee</th>
<th>Approval Status</th>
<th>Date of Approval</th>
<th>Is Independent Ethics Committee?</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMLH</td>
<td>Approved</td>
<td>26/10/2015</td>
<td>No</td>
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### Regulatory Clearance Status from DCGI

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>No Date Specified</td>
</tr>
</tbody>
</table>

### Health Condition / Problems Studied

<table>
<thead>
<tr>
<th>Health Type</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>CATARACT</td>
</tr>
</tbody>
</table>

### Intervention / Comparator Agent

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Group B</td>
<td>Torsional phacoemulsification using miniflare tip with IOP fed infusion system</td>
</tr>
<tr>
<td>Intervention</td>
<td>Group C</td>
<td>Torsional phacoemulsification using balanced tip with IOP fed infusion system</td>
</tr>
<tr>
<td>Comparator Agent</td>
<td>Group A</td>
<td>Torsional phacoemulsification using miniflare tip with gravity fed infusion system</td>
</tr>
</tbody>
</table>

### Inclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tbody>
<tr>
<td>Age From</td>
</tr>
<tr>
<td>Age To</td>
</tr>
<tr>
<td>Gender</td>
</tr>
</tbody>
</table>
| Details | 1. Grade 4.0-6.9 (LOCS III grading) of senile cataract  
2. Willing and able to understand /sign a written informed consent document  
3. Willing and able to return for scheduled follow-up examinations. |
**Exclusion Criteria**

| Details                                                                 | 1) Patients with pre-operative endothelial cell density count less than 1500 cells/mm²  
2) All eye pathologies that can compromise the visual recovery  
3) Eyes with any kind of corneal dystrophy or corneal scars preventing visualisation of cataract for reliable grading  
4) Subluxated or dislocated lens  
5) Raised intraocular pressure (> 21 mmHg)  
6) Previous intraocular surgery |

**Method of Generating Random Sequence**
- Coin toss, Lottery, toss of dice, shuffling cards etc

**Method of Concealment**
- Sequentially numbered, sealed, opaque envelopes

**Blinding/Masking**
- Participant and Outcome Assessor Blinded

**Primary Outcome**
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative dissipated energy (CDE)</td>
<td>PEROPERATIVE</td>
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**Secondary Outcome**
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated fluid volume usage</td>
<td>Peroperative</td>
</tr>
</tbody>
</table>
| Visual Acuity                                | Baseline  
One Month |
| Endothelial cell density                     | Baseline  
1 month  
3 months  
6 months |
| Coefficient of variation of cell size        | Baseline  
1 month  
3 months  
6 months |
| Percent Hexagonality                         | Baseline  
1 month  
3 months  
6 months |
| Central Corneal Thickness                    | Baseline  
1 month  
3 months  
6 months |

**Total Sample Size**
- Total Sample Size = 126
- Sample Size from India = 126

**Phase of Trial**
- Phase 4

**Date of First Enrollment (India)**
- 02/11/2015

**Date of First Enrollment (Global)**
- No Date Specified

**Estimated Duration of Trial**
- Years = 1  
- Months = 5  
- Days = 0

**Recruitment Status of Trial (Global)**
- Not Applicable

**Recruitment Status of Trial (Global)**
- Closed to Recruitment of Participants
<table>
<thead>
<tr>
<th>Trial (India)</th>
<th>Publication Details</th>
<th>Brief Summary</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Presently being analysed for primary objective and 2 secondary objectives assessed peroperatively</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REST OF ANALYSIS TO BE DONE AT THE END OF FOLLOWUP PERIOD</td>
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</tbody>
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