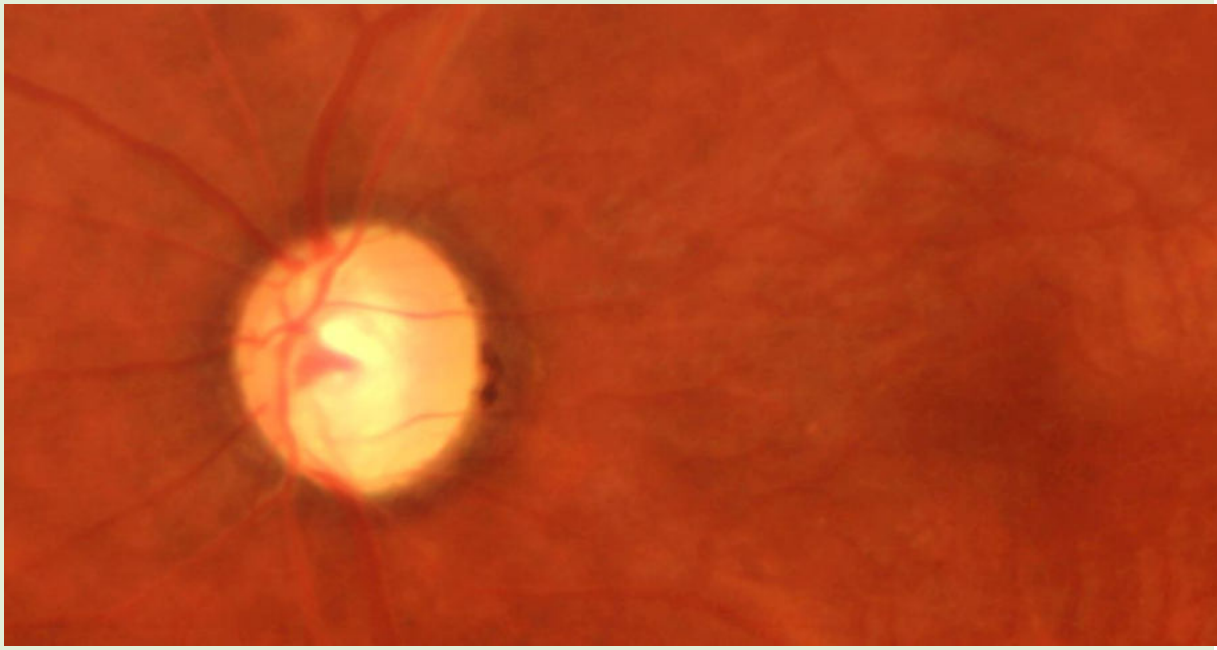
Glaucoma Society of India

GSI Newsletter

Issue No 5; May 2024



https://www.glaucomasociety.in/

Team Newsletter

Dr Julie Pegu

Dr Paaraj Dave

Dr Parivadhini A

Dr Shahinur Tayab

Dr Swati Upadhyaya

Editorial

Dear seniors, friends, and colleagues

Greetings from the GSI newsletter editorial team.
We received photos and communications of World Glaucoma Week celebrations from across India. Some of the events are compiled for your view in this issue of the newsletter.
The cover story of this issue briefs various ongoing trials in glaucoma. I hope this will interest you, and update you about new drugs and devices in the pipeline, which will add to your treatment regimen in the future.

The society and local organizing committee of GlaucoCherry 2024 is working in full swing for the 33rd annual conference. The registration link and important dates are made available for your convenience.
The amended constitution of the society (2024) has been uploaded to the website of the society and a link for the same is being shared in this newsletter.
Happy reading, and as always, your suggestions and feedback are awaited

Yours

Dr Parveen Rewri
Editor
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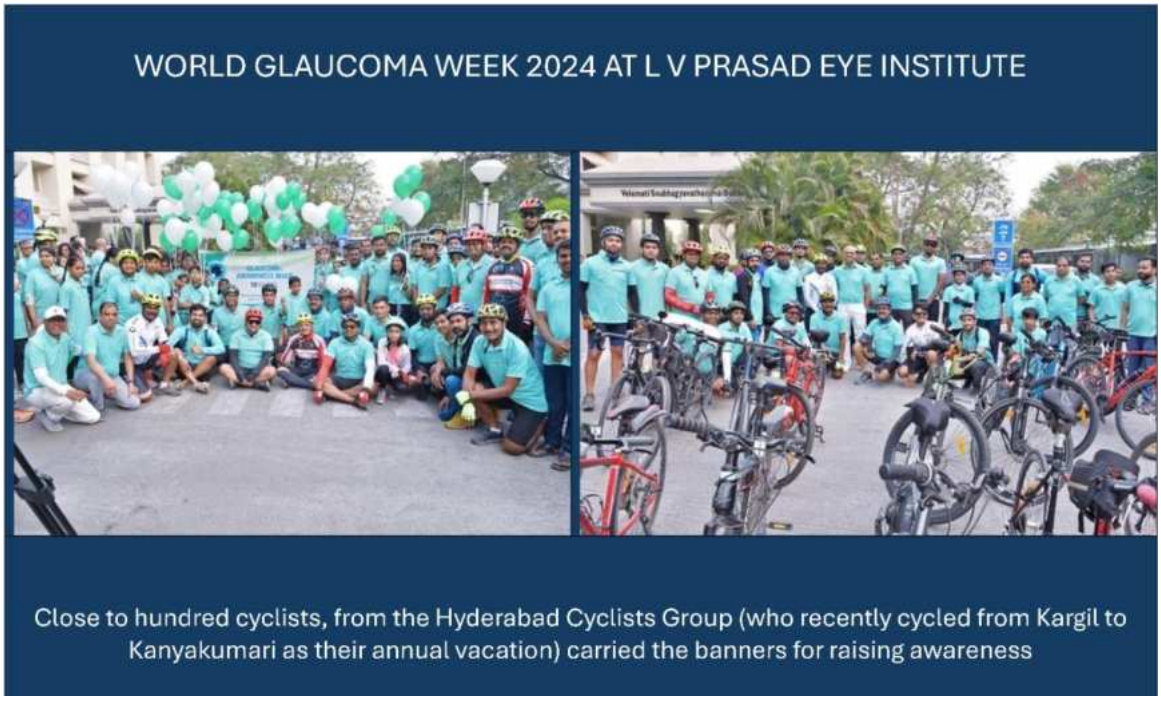
Glimpses: World Glaucoma Week 2024 Celebrations



Glaucoma Screening Camp
@Kovilpatti & @kanyakumari

World Glaucoma Week 2024 Awareness Campaign
IMA & Hisar Ophthalmological Society

Ongoing Clinical Drug Trials in Glaucoma

A lot is happening in field of pharmacotherapy of glaucoma. A few new molecules are being evaluated and newer drug delivery system are being tested. Drug implants may be new sensation in medical management of glaucoma, and may help to better compliance and reduce adverse effects. We brief about few on going drug and drug-implant trials here.

A Phase 1b Study of ONL1204 Ophthalmic Solution in Patients with Progressing Open Angle Glaucoma

The aim is to demonstrate the safety and tolerability of ONL1204 Ophthalmic Solution in patients with progressing open-angle glaucoma.

ONL1204 Ophthalmic Solution is a first-in-class inhibitor of fragment apoptosis stimulator (Fas) receptor-mediated cell death that has demonstrated the protection of multiple retinal cell types in numerous preclinical models of retinal disease. Apoptosis of retinal ganglion cells is associated with progressive glaucoma. Nonclinical data on ONL1204 Ophthalmic Solution suggest that ONL1204 Ophthalmic Solution may inhibit the cell death pathways in these cells.

18-Month Prospective Efficacy and Safety Study of Bimatoprost Intracameral Implant (DURYSTA) (ARGOS)

Study to collect effectiveness and safety data after administration of a bimatoprost intracameral implant in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

A Study to Evaluate the Efficacy and Safety of OTX-TIC (Travoprost) Intracameral Implant for Patients with Open-angle Glaucoma (OAG) or Ocular Hypertension (OHT)

This is a prospective, multicenter, randomized, parallel-group, controlled study to evaluate the efficacy and safety of OTX-TIC (travoprost) intracameral implant in subjects with open-angle glaucoma (OAG) or ocular hypertension (OHT). Approximately 105 subjects will be enrolled in this study at approximately 20 sites in the US. Subjects will be randomized to one of three treatment groups OTX-TIC drug product (2 travoprost dose strengths) compared to a single injection of DurystaTM.

24-hour IOP control with Travoprost/Timolol fixed combination compared with Latanoprost/Timolol fixed combination in exfoliative glaucoma

This phase 4 interventional trial compares 24-hour IOP control and safety after 3 months of therapy with Travoprost/Timolol fixed combination, versus that of Latanoprost/Timolol fixed combination when both are given once in the evening in patients with exfoliative glaucoma. This is a crossover, randomized, single (investigator) masked study with the primary purpose of treatment. The primary outcome measure is Travoprost/Timolol fixed drug combination will demonstrate better quality of 24-hour IOP control than Latanoprost/Timolol. The secondary outcome measure is the incidence of side effects with the two medications.

DE-117 ophthalmic solution monotherapy and concomitant use of DE-117 with Timolol 0.5% in OAG or ocular hypertension

This is randomized, open label phase 3 trial with parallel assignment evaluating the long-term safety and intraocular pressure lowering efficacy of DE-117 ophthalmic solution monotherapy and concomitant use of DE- 117 with Timolol ophthalmic solution 0.5% in patients with open angle glaucoma or ocular hypertension.

Travoprost APS versus Xalatan in patient reported outcomes and ocular surface health

This is a double-masked randomized phase 3 trial with parallel assignment interventional trial to understand the differences in visual function related patient reported outcomes between a non-BAK medication (Travoprost APS 40 micrograms/ml, 1 drop once daily in the evening for 90 days) and a BAK-preserved medication (XALATAN – Latanoprost 50 microgram/ml, 1 drop in evening for 90 days) in patients with open-angle glaucoma or ocular hypertension. The primary outcome measure is the mean NEI VFQ-25 composite score and the secondary outcome measure is the percent of patients with a corneal fluorescein staining score of 0 at the end of treatment period (day 90).

Ocular signs and symptoms in glaucoma patients switched from Latanoprost 0.005% to preservative free Tafluprost eye drops

This unmasked, open labeled phase 3 interventional trial is studying effects of preservative free Tafloprost on ocular surface related symptoms and/or signs in patients of ocular hypertension or open angle glaucoma using Latanoprost 0.005%. The primary outcome measure is change in ocular surface related symptoms and signs at 6 and 12 weeks from baseline. The secondary outcome measure is safety and quality of life parameters measured from the time of screening (first visit) to visits at weeks 2,6 and 12.

Efficacy and safety of once-daily instillation of combination glaucoma therapy in patients with open-angle glaucoma or ocular hypertension

This phase 3 interventional trial is to evaluate the intraocular pressure lowering efficacy of a combination IOP- lowering therapy in patients with open angle glaucoma or ocular hypertension. This is double masked randomized trial with parallel assignment and primary purpose of treatment with Travoprost 0.004%/ Timolol maleate 0.5% and Latanoprost 0.005%/ Timolol 0.005% over 12 months.

The impact of topical prostaglandins on the biomechanical properties of the cornea in patients with open angle glaucoma

This is an open label phase 4 interventional trial with single group assignment determining the influence of topical prostaglandin analog (PGA) medication on corneal biomechanical properties in patients undergoing PGA treatment for open angle glaucoma. 35 patients with bilateral eye OAG on monotherapy with topical PGA medications in both eyes were recruited. The primary outcome measure is corneal hysteresis difference in patients with PGAs and without PGAs based on the integrated analysis of the data collected from Reichert ocular response analyzer (ORA) in time frame of 12 weeks. The secondary outcome measures are the difference in IOP, corneal thickness and corneal resistance factor in patient with PGAs and without PGAs based on the integrated analysis of the data collected from Goldmann tonometry, pachymetry

and Reichert ocular response analyzer respectively.

Phase 3 Study Evaluating Safety and Efficacy of OTX-TP in Subjects with OAG or OHT

This was a prospective, multicenter, randomized, parallel-arm, double-masked, placebo vehicle-controlled study conducted to evaluate the safety and IOP-lowering efficacy of OTX-TP, a sustained release drug product placed in the canaliculus of the eyelid in subjects with open-angle glaucoma or ocular hypertension. A total of up to 550 subjects (1100 eyes) with a clinical diagnosis of open-angle glaucoma or ocular hypertension in both eyes received either OTX-TP or PV to evaluate the safety and efficacy of OTX-TP

Open Label, Sequential-dose Study of PA5108 Latanoprost FA SR Ocular Implant for Mild-moderate Glaucoma

This is a multi-centre, open label, interventional, comparative, phase Ib dose ranging study to identify a safe and efficacious dose (within the range of 14.7 to 35.5 microgram) of PA5108 Latanoprost FA SR Ocular Implant in adults who have POAG.

The proposed study is a single ascending dose design to determine the minimum effective dose that provides the target of >20% IOP lowering effect at 12 weeks with minimal adverse events.

Travoprost Intraocular Implant in Conjunction with Cataract Surgery

This is a multicenter, open-label, single-arm trial to evaluate the safety and efficacy of iDose® TR (Travoprost Intraocular Implant) in conjunction with cataract surgery. Subjects with cataract requiring extraction and who have open-angle glaucoma or ocular hypertension will undergo screening and washout from IOP-lowering medication, if applicable. Eligible subjects who meet all inclusion criteria and none of the exclusion criteria and who undergo successful cataract extraction with implantation of a posterior chamber intraocular lens will receive a travoprost intraocular implant and followed up for 12 months.

NT-501 CNTF Implant for Glaucoma: Safety, Neuroprotection and Neuroenhancement

Ciliary Neurotrophic Factor (CNTF) has been demonstrated in multiple pre-clinical models to enhance survival and regeneration of retinal ganglion cells; the retinal neurons injured in diseases like glaucoma. We hypothesize that CNTF delivery to the human eye will provide neuroprotection (prevent loss of vision) and neuroenhancement (improve vision indices) in glaucoma. Patients in the trial will receive an NT-501 CNTF implant (made by Neurotech) into one eye, and will be carefully followed to evaluate safety and efficacy

Study of NT-501 Encapsulated Cell Therapy for Glaucoma Neuroprotection and Vision Restoration

This is a randomized, sham controlled, masked clinical trial of 60 study participants with glaucoma. Participants with a qualifying study eye will be randomized after screening and baseline evaluations to receive the NT-501 encapsulated cell therapy (ECT) implant or a sham surgery (control arm), and no explant will be required.

An examination for safety will occur one day and one week following implant and periodically thereafter for 24 months post-implant. Based on the primary analysis of data at 6 months, patients in the control arm may be offered the NT-501 ECT implant at the 12-month time point.

Open Label, Sequential-dose Study of PA5108 Latanoprost FA SR Ocular Implant for Mild-moderate Glaucoma

This is a multi-centre, open label, interventional, comparative, phase Ib dose ranging study to identify a safe and efficacious dose (within the range of 14.7 to 35.5 microgram) of PA5108 Latanoprost FA SR ocular implant in adults of POAG. The proposed study is a single ascending dose design to determine the minimum effective dose that provides the target of >20% IOP lowering effect at 12 weeks with minimal adverse events.

Evaluation of the Duration of Effect of Bimatoprost SR in Participants with Open-Angle Glaucoma or Ocular Hypertension

This phase 3b study evaluates the duration of intraocular pressure (IOP)-lowering effect and safety of as needed administrations of Bimatoprost sustained release (SR) in participants with open-angle glaucoma or ocular hypertension who are not adequately managed with topical IOP-lowering medication for reasons other than medication efficacy.

Anecortave Acetate Safety in Patients with Open-Angle Glaucoma or Ocular Hypertension

The purpose of this study was to evaluate the safety and intraocular-lowering efficacy of anecortave acetate depot when administered by anterior juxtascleral depot (AJD) for the treatment of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Safety Assessment of T4090 Eye Drops in Ocular Hypertensive or Glaucomatous Patients.

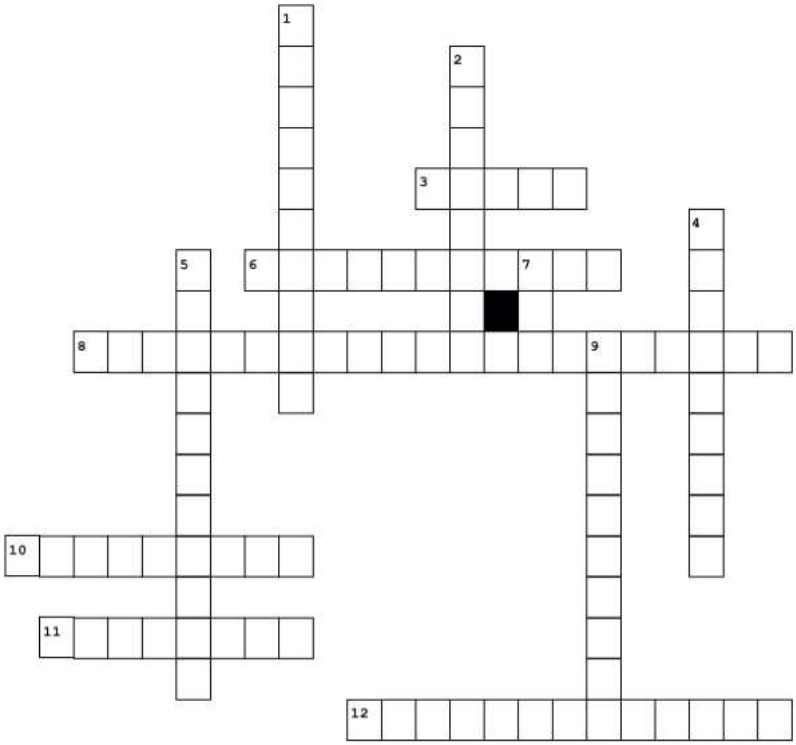
The purpose of the study is to evaluate the safety of T4090 (Kinezodianone R hydrochloride) in ocular hypertensive or glaucomatous patients.

The information on ongoing drug and drug implant trials is sourced from the web site of clinical trials (Available at-https://clinicaltrials.gov/), and is compiled by *Dr Ridhima Sardana*, a post-graduate student at Maharaja Agrasen Medical College, Agroha (Hisar).

Have you read the constitiuion of Glaucoma Society of India?

The amended constitution 2024 of GSI has been uploaded on the GSI website. Click here to read.

re-SOLVE Glaucoma



Across

3. This study showed SLT to be clinically and economically effective as a primary treatment of open-angle glaucoma

6. Antiglaucoma drug of pregnancy class B

8. Visual hallucinations caused by the brain's adjustment to significant vision loss, often seen in glaucoma

10. Technique that precisely measures the real pressure inside the eye

11. Developer of the latest glaucoma drainage device

12. Drug group not present in the newest triple drug combination

Down

1. Newest FDA-approved intracameral drug for implantation

2. Newest istent

4. Derived from Streptomyces caespitosus

5. Regular refilling of the prescribed therapy, until the first discontinuation

7. A preservative containing zinc chloride, borate, propylene glycol, and sorbitol is popularly known as.

9. Drug possibly liked by bees due to its effect

Compiled by Dr Purvi Bhagat

Dr Purvi Bhagat is Professor & Head of Glaucoma Services at M & J Western Regional Institute of Ophthalmology B. J. Medical College Ahmedabad, Gujarat. Glaucoma- crossroads challenge this time is titled to re-solve glaucoma.

Mail your entries to gsinewseditor@gmail.com. The first three correct entries will feature in the next issue of the e-newsletter.

Winners of last quiz: **Dr Prasanna Ramesh (Trichy), Dr Lipi Chakrabaty (Durg)**

To register for the Annual Conference of GSI from 27-29 September 2024 at Suganya Conventional Centre, Puducherry *click here*

IMPORTANT DATES

- Submission starts of abstracts - 10/05/2024
- Last date of submission of abstracts - 10/06/2024
- Intimation of assessment of abstracts - 10/07/2024
- Submission of full videos -11/07/2024 to 15/08/2024
- Submission of full text of accepted oral papers - 15/09/2024

GSI ELECTIONS 2024

Elections will be held online for the following posts

- President - One
- General Secretary - One
- Treasurer - One
- Zonal Member - Five (one in each zone)

The timeline will be made public soon. Eligibility for these posts can be checked in the constitution available on the website.

Bids for GSI Annual Conference 2026

Bids for hosting the 35th Annual Conference of GSI will be invited from the members of the east zone. The notice for this will be uploaded on the website soon. *The last date for sending the bids is 31/07/2024*