Clarifying the Optimal Application of SLT Therapy (COAST) Trial: Study Synopsis

Study Objective:

1. To compare the intraocular pressure (IOP)-lowering efficacy of standard energy SLT versus low energy SLT
2. To compare the long-term medication-free survival with SLT repeated as needed (PRN) versus repeated annually

Study Treatments:

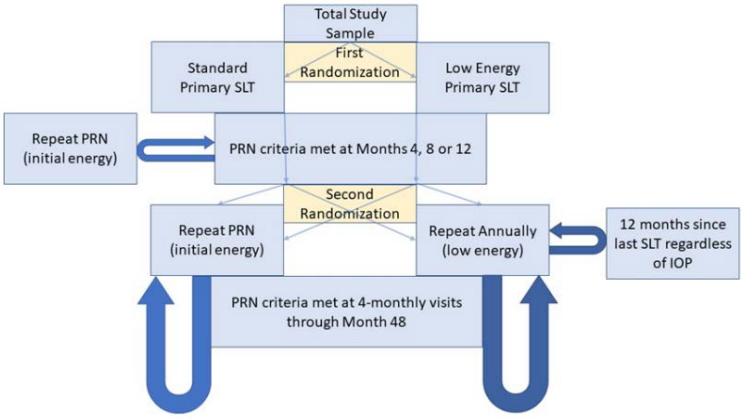
- Standard SLT will be performed as follows: beginning at 0.8 mJ, energy will be titrated up or down within the first 5-10 spots until champagne bubbles are visualized with every 2nd or 3rd spot. Energy can be titrated throughout the procedure, in response to variations in pigmentation, to ensure the appearance of champagne bubbles with every 2nd or 3rd spot throughout the full 360° treatment. Energy should be increased if no bubbles are seen with 5 consecutive spots and decreased if bubbles are seen with 5 consecutive spots.
- Low energy SLT will consist of 100 treatment spots delivered at 0.4mJ per spot throughout the full 360° treatment, with the exception that energy can be reduced to 0.3mJ if bubbles are seen with 5 consecutive spots and can be increased back to a maximum of 0.4mJ if no bubbles are seen with 5 consecutive spots.
- Regardless of energy level randomization, energy may be adjusted downward in 0.1mJ increments throughout the procedure in response to factors such as heavy focal pigmentation or patient discomfort.
- In eyes with heavy angle pigment, investigators may elect to deliver the full 360° treatment in 2 staged sessions of 180° each, no more than 2 weeks apart, to minimize the risk of post-SLT IOP elevations.

Study Population:

Treatment-naïve patients with mild-moderate primary open-angle glaucoma (POAG) or high-risk ocular hypertension (OHT). Full eligibility criteria given at the end of this document.

Study Design:

COAST is a consecutive pair of prospective multicenter randomized trials in which patients are randomized first to standard energy versus low energy SLT as primary therapy, and at 12 months are re-randomized to PRN ("Treat and Wait") versus annual ("Treat and Repeat") repeat SLT.



Study Outcomes:

1. 12-month survival of initial SLT (survival defined as attaining and maintaining disease- and severity-specific target IOP) with a single SLT treatment
2. 48-month medication-free survival (same definition as above) with SLT repeated as needed
3. Safety outcomes to include incidence and frequency of adverse events

Schedule of Visits:

Procedures	Eligibility Day –14 to –1	Baseline Day –7 to 0	Treatment Day 0	Month 1 ± 3 d	Month 4 ± 7 d	Month 8 ± 14 d	Month 12 ± 30 d	Every 4 mo through Month 44 ± 30 d	Month 48 ± 30 d
Informed consent	X								
Contact and emergency contact	X								
Demographics	X								X
Medical history	X	X	X	X	X	X	X	X	X
Visual acuity	X	X	X	X	X	X	X	X	X
Intraocular pressure	X	X	X	X	X	X	X	X	X
Gonioscopy	X						X	X*	X
Pachymetry	X								X
Anterior segment examination	X	X	X	X	X	X	X	X	X
Dilated posterior segment examination	X						X	X*	X
Automated visual field	X	X					X	X*	X
Ocular biometry		X							
Optical Coherence Tomography	X						X	X*	X
Randomization		X[1]					X[2]		X
Laser treatment			X		PRN	PRN	PRN	PRN	PRN
Adverse event review and evaluation		X	X	X	X	X	X	X	X
Complete Case Report Forms (CRFs)	X	X	X	X	X	X	X	X	X

*Months 24 and 36 only

1. First randomization to initial standard versus initial low energy SLT

2. Second randomization to repeat SLT as needed (at first-randomized energy) or annual low energy repeat SLT

Budget:

Study-related services will be paid on a per-service, per-visit basis. The total payment for a participant completing the full 4-year study is approximately $6,755.00 USD and will vary somewhat based on the frequency of as-needed assessments and treatments.

Full Eligibility Criteria:

Inclusion criteria:

1. Good general health
2. Ability to provide informed consent
3. Age 18 years or older
4. Diagnosed with one of the following in the study eye:
    a. Ocular hypertension: IOP > 21 mmHg without glaucomatous optic neuropathy (excavation, diffuse or focal thinning or notching of the neuroretinal rim, visible nerve fiber layer defects, or asymmetry of the vertical cup-to-disc ratio of ≥0.2 between eyes) [enrollment of subjects with OHT will be capped at 25% of total enrollment]
    b. Early primary open-angle glaucoma: glaucomatous optic neuropathy, visual field mean deviation >-6.0 dB with no points in the central 5° <15 dB
    c. Moderate primary open-angle glaucoma: glaucomatous optic neuropathy, visual field mean deviation -6.0 dB to ≥-12 dB and no more than 1 central 5° point <15 dB
5. Newly diagnosed, treatment naïve (no prior IOP-lowering treatments), and with a decision to treat made by an ophthalmologist on the basis of risk profile, patient preference, or both

Exclusion criteria:

1. Advanced POAG
2. Glaucoma other than POAG (including pigmentary and pseudoexfoliation glaucoma)
3. IOP > 35 mmHg at either the screening or baseline visit
4. Narrow or closed angle (Shaffer Grade 0, 1, or 2)
5. Best-corrected visual acuity less than 20/200 in the study eye
6. Contraindications to SLT
7. Contraindications to brimonidine
8. Any corneal pathology that would preclude accurate assessment of IOP by Goldmann tonometry
9. Any intraocular surgical procedure within the past 6 months
10. Inability to attend all scheduled study visits