

BAUCHI LASER STUDY- ANALYSIS PLAN

This is primarily a feasibility study, not a definitive superiority trial, so the analysis emphasises feasibility, estimates, precision and uncertainty rather than simply testing whether one laser is “better”.

We are still working on cleaning the data and getting the final results. Results presented here are not final.

Study population and analysis cohorts

- * Analyse the 283 recruited participants while preserving the distinction between:
 - * Pre-amendment cohort: SLT, MLT and TLT.
 - * Post-amendment cohort: SLT and MLT only, following discontinuation of TLT because of unacceptable pain.

1. Feasibility outcomes

The primary analysis will describe whether a definitive RCT is practicable, including:

- * recruitment rate and recruitment experience;
- * eligibility, participation and refusal rates;
- * reasons for refusal/non-participation;
- * treatment delivery and treatment completion;
- * attendance and retention at each follow-up point;
- * ability to collect outcome data;
- * adherence to allocated treatment and additional glaucoma medication;
- * need for rescue/retreatment;
- * equipment, logistical and operational difficulties.

Recruitment and follow-up will be reported using numbers and percentages with appropriate denominators, rather than relying only on percentages.

2. Baseline characteristics

Describe baseline demographic and clinical characteristics by treatment group:

- * age and sex;
- * baseline IOP;
- * visual acuity;
- * glaucoma severity/VCDR;
- * relevant ocular characteristics;
- * medication and other important baseline variables.

Continuous variables will generally be presented as mean (SD); categorical variables as number (%).

3. IOP efficacy

IOP will be summarised at:

baseline, 1 hour, 1 week, 1 month, 2, 3, 4, 6 and 12 months.

At each time point:

- * report the number of participants/eyes available;
- * mean/SD
- * change from baseline;
- * percentage reduction from baseline;

- * treatment-group estimates with 95% confidence intervals.

4. Treatment success

Success will be analysed using the predefined IOP targets:

- * Threshold 1: <19 mmHg

- * Threshold 2: <22 mmHg

Report:

- * absolute number achieving target;

- * percentage achieving target;

- * 95% CI;

- * comparison between treatment groups where appropriate.

Complete success and qualified success will also be reported, distinguishing patients achieving target without additional medication from those achieving target with medication.

5. $\geq 30\%$ IOP reduction

The proportion achieving a $\geq 30\%$ reduction from baseline IOP will be assessed at the follow-up time points, with estimates and 95% CIs and exploratory comparisons between treatment groups.

6. Statistical comparisons

The study is not powered primarily to establish superiority between lasers. Therefore:

- * comparisons between SLT and MLT will be considered exploratory;

- * TLT will be described separately as the pre-amendment cohort;

- * effect estimates and 95% CIs will be emphasised alongside p-values;

- * where appropriate, chi-square/Fisher's exact tests will be used for categorical outcomes and suitable parametric/non-parametric methods for continuous outcomes.

Where data structure permits, adjusted analyses may be considered for important baseline differences, but these should not obscure the principal feasibility objective.

7. Missing data

Missingness will be described by:

- * treatment group;

- * follow-up time;

- * relevant baseline characteristics.

8. Safety and patient experience

Analyse:

- * IOP spikes;

- * visual acuity loss;

- * other ocular adverse events;

- * rescue treatment;

- * repeat laser treatment;

- * treatment-related pain;

- * POEM/patient experience measures.

TLT's substantially greater pain burden and subsequent discontinuation are particularly important feasibility findings.

9. Data quality and audit

Before final analysis, conduct a structured data audit for: (We are doing these new)

- * impossible or extreme values;
- * internally inconsistent values;
- * implausible sudden changes in IOP;
- * duplicated/mismatched records;
- * date inconsistencies;
- * discrepancies between derived and source variables.

10. Final reporting

The planned principal outputs are:

1. Baseline characteristics table
2. Recruitment, retention and follow-up/feasibility table
3. IOP trajectory and treatment-effect analysis
4. Success and $\geq 30\%$ IOP-reduction analyses
5. Safety/adverse-event analysis
6. Patient experience/POEM analysis
7. Flow diagram showing recruitment, allocation, follow-up and analysis
8. Clear separation of pre-amendment TLT data from the amended SLT/MLT comparison.