MO-HO trial (MOLEP vs HOLEP)

Study Protocol

1) Title

MOHO Trial: A prospective, randomized study comparing MoLEP vs HoLEP for BPH (50–250 cc) using the Lumenis Moses 2.0 platform.

2) Objectives & Endpoints

Primary endpoint:

- Enucleation efficiency (g/min): enucleated tissue weight / enucleation time (to detect differences in precision/cutting efficiency)

Key secondary endpoints:

- Hemoglobin drop (g/dL): pre-op Hb minus post-op Hb at ~24±6 hours.
- Total operative time (min): from first laser activation to scope-out.
- Laser energy per gram (kJ/g): total delivered laser energy / enucleated weight.
- Need for irrigation > 1 day.
- Return to OR for hemostasis within 10 days.
- LOS (days).
- Need for transfusion (yes/no; units).

3) Design

- Prospective, randomized, parallel-group, single-center (Saint Luke's Hospital, Greece).
- Allocation ratio: 1:1 (MOLEP vs HoLEP).
- Blinding: Surgeon cannot be blinded; outcome assessors, data abstractors, and statisticians blinded to group allocation.

4) Eligibility

Inclusion criteria

- Age ≥45 years.
- Symptomatic BPH or ARI (acute retention of urine) indicated for enucleation.
- Prostate volume 50–250 cc (US or MRI within 6 months).

- Ability to provide informed consent.

Exclusion criteria

- Peri-operative need for therapeutic anticoagulation/antiplatelet therapy (beyond low-dose LMWH prophylaxis or low-dose aspirin ≤100 mg/day — these are allowed and will be analyzed in sub-analysis).
- Known/suspected prostate cancer requiring oncologic surgery.
- Prior prostate surgery for BPH (TURP/HoLEP/open).
- Active UTI (must treat and re-schedule).
- Neurogenic bladder.
- Uncorrected coagulopathy.
- ASA IV–V.

5) Interventions

- Same surgeon with experienced in holmium laser enucleation of prostate with >1000 procedures.
- Similar energy settings (50Hz – 1.6J = 80 Watts for cutting, 30Hz – 2J=60 Watts for coagulation).
- MOLEP arm: Lumenis Moses 2.0 with single-use Moses fiber (double-pulse “bubble” technology).
- HoLEP arm: Same platform using standard multi-use HoLEP fiber.
- Patient positioning, irrigation pressure, morcellation, hemostasis, catheter management per standardized SOP applied equally to both arms.
- Enucleation technique (2-lobe, 3-lobe or en-bloc—permit both but record which).

Same iv fluids and eating habits during hospitalization (80ml/min R/L)

6) Randomization & Allocation

- Central, computer-generated with stratification by: prostate volume bands: 50–100, 101–150, 151–250 cc
- Sealed opaque envelopes opened after induction and before fiber setup to minimize bias.

7) Sample Size (planning for 200 total)

- For primary endpoint (enucleation efficiency (g/min)) expect Δ=0.5 g/min with SD≈1.2, two-sided α=0.05, power 80% ⇒ ~91 per arm.

8) Precise Definitions

- Operative time: first laser shot to catheter placement.
- Enucleation time: first laser shot for enucleation until adenoma completely detached (prior to morcellation).
- Enucleated weight (g): pathology scale (dry weight).
- Laser energy (kJ): machine-logged total delivered energy (export or photo of console).
- Hb drop (g/dL): pre-op Hb (≤30 days; ideally day-of) minus first post-op Hb at ~24±6 hours.
- Return to OR/intervention for hemostasis ≤10 days: includes cystoscopic clot evacuation, return to laser, or angio-embolization. ED visits for retention/clot retention recorded.

9) Data Collection & Visits

- Baseline: demographics, comorbidities (incl. COPD), meds (antithrombotics), PSA, prostate volume.
- Intra-op CRF: allocation, technique (3-lobe vs en-bloc), console-reported energy (kJ), times (operative, enucleation, morcellation), events, transfusion, capsular perforation, conversion.
- Post-op (inpatient): Hb at ~24 h, catheter status, LOS, complications.
- Day 10 (±3) phone/clinic: bleeding episodes, ER/OR returns, catheter issues.

10) Statistical Analysis Plan

- Analysis set: Intention-to-treat (primary). Per-protocol sensitivity (exclude major protocol deviations).
- Primary endpoint: Compare groups with adjustment for baseline prostate volume band; report adjusted mean difference with 95% CI.
- Key secondary: Same model family; for binary outcomes (return to OR), use logistic regression with same covariates; report adjusted OR with 95% CI.

11) Safety & Monitoring

- Stopping rules: excessive return-to-OR for bleeding or transfusions in one arm
- AE reporting: within 24–72 h to PI and hospital IRB/ethics as per policy.

12) Ethics & Governance

- Approval: Saint Luke's Hospital Ethics/IRB.

13) Logistics & Quality Control

- Surgeon experience: all cases bu single high-volume surgeon (more 1000 surgeries) to avoid learning-curve confounding.
- Training & calibration: brief the theater team; standardize irrigation pressures; record any deviations.

14) Sub-Analyses (pre-specified)

- By prostate volume band (50–100 / 101–150 / 151–250).
- By antithrombotic status (low-dose allowed vs none).
- By technique (3-lobe vs en-bloc).