Postgraduate year one OB/GYN residents (PGY1) were randomized into Control (C) or Intervention (I) groups. Both groups completed on-line pre-test and standard site-specific resident curriculum. Intervention group additionally utilized the LHT-Simpraxis®. After two months both groups completed post-test.

Results: Phase One: Sixty RF completed tests A.B. Forty took A first; twenty took B first. There was no significant difference in scores between the 2 versions, establishing test reliability (linear regression \( P = 0.565; \) t-test \( P = 0.366 \)). RF test A scores (77%) were significantly higher than PGY1 score (47%), \((P < 0.001, 95\% CI 141.53, 180.13),\) establishing construct validity. Phase Two: There was no significant difference in pre-test scores between groups, \((C = 49\%, I = 43\%; \) \(P = 0.089 \)). Intervention group scored significantly better on post-test, \(C = 59\%, I = 69\% \) (t-test: \(P < 0.001, 95\% CI -108.8, -48.4 \)). There was a significant difference in post- vs. pre-test scores \((P = 0.0002, 95\% CI -80.10, -26.55) \).

Conclusion: Two reliable and valid on-line tests were developed that can be utilized independently to assess cognitive surgical knowledge of LH. Use of the LHT-Simpraxis® significantly improved PGY1 residents’ surgical knowledge of LH.

Primary efficacy and safety results from two double-blind, randomized, placebo-controlled studies of elagolix, an oral gonadotropin-releasing hormone antagonist, in women with endometriosis-associated pain

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Objectives: Two similar, double-blind, randomized, placebo-controlled, multicentre, phase 3 studies (S1 [North America; NCT01620528], S2 [global; NCT01931670]) evaluated 6 months (M) of elagolix treatment, an oral, non-peptide gonadotropin-releasing hormone antagonist (150mg once-daily [QD; partial estradiol suppression] and 200mg twice-daily [BID; near full estradiol suppression]).

Study Methods: Participants were 18–49 year-old women with surgically diagnosed endometriosis and moderate/severe endometriosis-associated pain. Dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) scores on a 4-point scale were recorded in a daily electronic-diary. Adverse events (AE) and changes in bone mineral density were assessed.

Results: 871 women were randomized and treated, of which 653 (75%) completed S1. Compared to placebo, we report for the first time that elagolix treatment resulted in significant decreases in DYS scores at M1 through M6 (M6: LS mean [SE] percent change from baseline, placebo = -19% [2.2], elagolix 150 mg QD = -41% [2.7] \(P \leq 0.001,\) elagolix 200 mg BID = -80% [2.8] \(P \leq 0.001\)). Compared to placebo, elagolix treatment resulted in significant decreases in NMPP scores at M3 and M6 (M6: placebo = -18% [2.4], elagolix 150 mg QD = -31% [2.9] \(P < 0.01,\) elagolix 200 mg BID = -48% [3.0] \(P < 0.001\)). Hot flush, headache and nausea were the 3 most common AEs for elagolix-treated women. Elagolix treatment led to statistically significant, dose-dependent mean decreases from baseline to M6 in BMD compared with placebo, which was not of clinical concern with 150 mg QD. S2 results were similar.

Conclusion: Elagolix treatment was effective in reducing DYS and NMPP over 6 months. The elagolix safety/tolerability profile included dose-dependent hypoestrogenic effects, consistent with the mechanism of action.