**AUB KQ1 Evidence Table (Reference ID #802)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Lahteenmaki et al., 1998**Country:**Finland**Enrollment** **period:** November 1991 to December 1993**Intervention** **setting:** 3 clinics**Funding:**Leiras Oy, Turku,Finland**Author industry relationship disclosures:**None**Study Design:** RCT**Blinding:** None | **Intervention:**Levonorgestrel-releasing intrauterine system inserted according to instructions**Comparator:**Existing medical treatment**Groups:****G1:** LNG-IUS**G2:** Control (current medical treatment)**Followup:****G1:** 12 months **G2:** 6 months  | **Inclusion criteria:** * Women with spontaneous cycles scheduled to undergo hysterectomy for treatment of excessive uterine bleeding with or without dysmenorrhea

**Exclusion criteria:** One fibroid >3 cm in diameter or more than 3 uterine fibroids as assessed by ultrasonographyHistory or current malignancy or active liver diseaseAdnexal tumors or cystsPelvic Inflammatory Disease within the previous 12 months**N at enrollment:** **G1:** 28**G2:** 28**N at followup:** **G1:** 27**G2:** 26a **Age, mean years ± SD:****G1:** 42.7 ± 3.4**G2:** 41.7 ± 4.5**BMI:** NR**Parity:** NR**Race/ethnicity:** NR | **Menstrual disturbance:**General well being VAS, median (95% CI): **G1:** 90 (74, 94)**G2:** 87 (77, 92)**G1** **vs. G2:** p=NSWork performance VAS, median (95% CI):**G1:** 79 (62, 89)**G2:** 75 (61, 80)**G1** **vs. G2:** p=NSPhysical activity VAS, median (95% CI):**G1:** 88 (64, 95)**G2:** 78 (64, 92)**G1** **vs. G2:** p=NSSex life VAS, median (95% CI):**G1:** 68 (49, 86)**G2:** 66 (52, 80)**G1** **vs. G2:** p=NSLeisure time activity VAS, median (95% CI):**G1:** 76 (54, 86)**G2:** 74 (64, 85)**G1** **vs. G2:** p=NS  | **Bleeding:**Bleeding, median days per month:bMonths 1 to 3:**G1:** NR**G2:** NR**G1** **vs. G2:** p=NSMonths 4 to 6:**G1:** NR**G2:** NR**G1** **vs. G2:** p=NSSpotting, median days per month:bMonths 1 to 3:**G1:** NR**G2:** NR**G1** **vs. G2:** p=0.001Months 4 to 6:**G1:** NR**G2:** NR**G1** **vs. G2:** p=0.016**Menstrual disturbance:**General well being VAS, median (95% CI): 6 months:**G1:** 24 (14, 40)**G2:** 79 (64, 87)**G1** **vs. G2:** p<0.00112 months: **G1:** 10 (4, 29)**G2:** NRWork performance VAS, median (95% CI):6 months:**G1:** 20 (5, 35)**G2:** 76 (54, 87)**G1** **vs. G2:** p<0.00112 months:**G1:** 6 (3, 11)**G2:** NRPhysical activity VAS, median (95% CI):6 months:**G1:** 27 (9, 38)**G2:** 78 (55, 88)**G1** **vs.** **G2:** p<0.00112 months:**G1:** 10 (3, 28)**G2:** NRSex life VAS, median (95% CI):6 months:**G1:** 36 (17, 49)**G2:** 66 (51, 85)**G1** **vs.** **G2:** p=0.00212 months:**G1:** 8 (3, 28)**G2:** NRLeisure time activity VAS, median (95% CI):6 months:**G1:** 11 (5, 27)**G2:** 74 (54, 86)**G1** **vs.** **G2:** p<0.00112 months:**G1:** 6 (3, 29)**G2:** NR**Additional interventions:**Cancelled hysterectomy at 6 months, % (95% CI):**G1:** 64.3 (44.1, 81.4)**G2:** 14.3 (4.0, 32.7)**G1** **vs. G2:** p<0.001Underwent hysterectomy at 12 months, n (%):**G1:** 12 (57)**G2:** NRSwitched to LNG-IUS at 6 months, n: **G1:** NA**G2:** 2/26Continued with LNG-IUS at average followup of 3 years, n (%):**G1:** 13 (48)**G2:** NR**Adverse events, n:**Serious adverse events:**G1+G2:** 0 | **Overall quality:**Poor**Risk of bias:** Randomization: LowAllocation concealment:LowSelective reporting:UnclearBlinding patients/personnel:UnclearBlinding outcome assessment:HighIncomplete outcome reporting:LowOther:Low |

**Table Notes**: a At 6 months, two women in G2 switched to LNG-IUS; b Values only displayed graphically in Figures 1 and 3 (pg. 1124).