**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 ultrasonography  History or current malignancy or active liver disease  Adnexal tumors or cysts  Pelvic 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=NS  Work performance VAS, median (95% CI):  **G1:** 79 (62, 89)  **G2:** 75 (61, 80)  **G1** **vs. G2:** p=NS  Physical activity VAS, median (95% CI):  **G1:** 88 (64, 95)  **G2:** 78 (64, 92)  **G1** **vs. G2:** p=NS  Sex life VAS, median (95% CI):  **G1:** 68 (49, 86)  **G2:** 66 (52, 80)  **G1** **vs. G2:** p=NS  Leisure 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:b  Months 1 to 3:  **G1:** NR  **G2:** NR  **G1** **vs. G2:** p=NS  Months 4 to 6:  **G1:** NR  **G2:** NR  **G1** **vs. G2:** p=NS  Spotting, median days per month:b  Months 1 to 3:  **G1:** NR  **G2:** NR  **G1** **vs. G2:** p=0.001  Months 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<0.001  12 months:  **G1:** 10 (4, 29)  **G2:** NR  Work performance VAS, median (95% CI):  6 months:  **G1:** 20 (5, 35)  **G2:** 76 (54, 87)  **G1** **vs. G2:** p<0.001  12 months:  **G1:** 6 (3, 11)  **G2:** NR  Physical activity VAS, median (95% CI):  6 months:  **G1:** 27 (9, 38)  **G2:** 78 (55, 88)  **G1** **vs.** **G2:** p<0.001  12 months:  **G1:** 10 (3, 28)  **G2:** NR  Sex life VAS, median (95% CI):  6 months:  **G1:** 36 (17, 49)  **G2:** 66 (51, 85)  **G1** **vs.** **G2:** p=0.002  12 months:  **G1:** 8 (3, 28)  **G2:** NR  Leisure time activity VAS, median (95% CI):  6 months:  **G1:** 11 (5, 27)  **G2:** 74 (54, 86)  **G1** **vs.** **G2:** p<0.001  12 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<0.001  Underwent hysterectomy at 12 months, n (%):  **G1:** 12 (57)  **G2:** NR  Switched to LNG-IUS at 6 months, n:  **G1:** NA  **G2:** 2/26  Continued 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:  Low  Allocation concealment:  Low  Selective reporting:  Unclear  Blinding patients/personnel:  Unclear  Blinding outcome assessment:  High  Incomplete outcome reporting:  Low  Other:  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).