**AUB KQ1 Evidence Table (Reference ID #341)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality**  **Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Reid and Virtanen-Kari, 2005  **Country:**  United Kingdom  **Enrollment** **period:**  May 1996 to December 1998  **Intervention** **setting:**  District general hospital  **Funding:**  Schering Oy  **Author industry relationship disclosures:**  2/2  **Study Design:**  RCT  **Blinding:**  None | **Intervention:**  LNG-IUS, 52 mg levonorgestrel in cylinder initial release rate 20 µg per 24 hours  **Comparator:**  Oral mefenamic acid, 500 mg three times daily for first 4 days of cycle  **Groups:**  **G1:** LNG-IUS  **G2:** Mefenamic acid  **Followup:**  6 cycles | **Inclusion criteria:**   * Aged 18 to 47 years   Good general health with regular, ovulatory menstrual cycles of 21 to 35 days  Idiopathic menorrhagia (MBL ≥80 mL) confirmed in one cycle within 4 month period preceding study  **Exclusion criteria:**  Undiagnosed abnormal bleeding  Anovulatory  Submucous fibroids or fibroids with total volume of >5 cm3 defined by ultrasound scan  Uterine size of >10 cm  Abnormal cervical cytology  Untreated hypertension  Abnormal thyroid or liver function tests  Asthma  Intrauterine device  Treated for menorrhagia or used hormonal contraceptives within previous 4 months  **N at enrollment:**  **G1:** 25  **G2:** 26  **N at followup (cycle 6):**  **G1:** 21  **G2:** 21  **Age, mean years:**  **G1:** 39.4  **G2:** 38.5  **BMI:**  NR  **Parity:**  NR  **Race/ethnicity:**  NR | **Bleeding:**  MBL, measured by modified alkaline hematin technique, median ml (range):  **G1:** 122 (81, 375)  **G2:** 121 (85, 389)  Total menstrual fluid loss,a median mL (range):  **G1:** 183 (103-527)  **G2:** 211 (91-491)  PBAC score, median (range):  **G1:** 240 (91-545)  **G2:** 233 (77-469) | **Bleeding:**  MBL, measured by modified alkaline hematin technique, median ml (range):  Cycle 3:  **G1:** 12 (0, 240)  **G2:** 94 (29, 219)  **G1 vs. G2:** p<0.001  Cycle 6:  **G1:** 5 (0, 45)  **G2:** 100 (46, 168)  **G1 vs. G2:** p< 0.001  Total menstrual fluid loss, median mL (range):  Cycle 3:  **G1:** 53 (0, 459)  **G2:** 151 (57, 280)  **G1 vs. G2:** p<0.001  Cycle 6:  **G1:** 27 (0, 156)  **G2:** 157 (76, 319)  **G1 vs. G2:** p<0.001  PBAC score, median (range):  Cycle 3:  **G1:** 49 (0, 286)  **G2:** 161 (77, 262)  **G1 vs. G2:** p<0.001  Cycle 6:  **G1:** 25 (0, 402)  **G2:** 159 (50, 307)  **G1 vs. G2:** p<0.001  **Quality of life:**  NR  **Sexual function:**  NR  **Patient satisfaction:**  NR  **Fertility:**  NR  **Time to conception:**  NR  **Additional interventions:**  NR  **Adverse events, n:**  Abdominal pain:  **G1:** 8/25  **G2:** 2/26  Headache:  **G1:**10/25  **G2:** 10/25  Breast pain:  **G1:** 6/25  **G2:** 2/26  Nausea:  **G1:** 2/25  **G2:** 4/26  Diarrhea:  **G1:** 1/25  **G2:** 4/25  Upper respiratory infection:  **G1:** 5/25  **G2:** 5/26  LNG-IUS expulsion:  **G1:** 4/25  **G2:** NA | **Overall quality:**  Poor  **Risk of bias:**  Randomization:  Low  Allocation concealment:  Low  Selective reporting:  Unclear  Blinding patients/personnel:  High  Blinding outcome assessment:  High  Incomplete outcome reporting:  Low  Other:  Low |

**Table Notes:** a Total menstrual fluid loss was determined by difference in weight between returned sanitary material and original weight. Correlations between change in total menstrual fluid loss and PBAC scores over the six cycles when all patients were analyzed together (r=0.88, p<0.0001). PBAC scores correlated with changes in MBL (r=0.53, p= 0.0007) and total menstrual fluid loss (r=0.58, p=0.0002).