**AUB KQ1 Evidence Table (Reference ID #1179)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality**  **Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Vargyas et al., 1987  **Country:**  United States  **Enrollment** **period:**  NR  **Intervention** **setting:**  Academic medical center  **Funding:**  NR  **Author industry relationship disclosures:**  NR  **Study Design:**  RCT (crossover)  **Blinding:**  Patients, clinicians | **Intervention:**  Meclofenamate sodium (meclomen), 100 mg three times per day for two cycles followed by placebo for two cycles  **Comparator:**  Placebo, three times per day for two cycles, followed by meclomen for two cycles  Medication initiated after onset of menses and continued for 6 days or until end of menses whichever came first  **Groups:**  **G1:** Meclomen first then placebo  **G2:** Placebo first thenmeclomen  **Ga:** Meclomen  **Gb:** Placebo  **Followup:**  Observation phase: 2 months  Treatment phase: 2 months | **Inclusion criteria:**   * Aged 16 to 42 years   History of menorrhagia  >60 ml in one observation cycle  Negative pregnancy test  **Exclusion criteria:**  Anovulatory cycles (proliferative endometrium)  Histological evidence of pathological changes in the endometrium (hyperplasia or atypia)  Extrauterine disease  Palpable leiomyoma  Known sensitivity to fenamates  Anticoagulant therapy  Thyroid dysfunction  Hepatic disease  Renal disease  Abnormal cervical cytological findings  **N at enrollment:**  **G1:** 15  **G2:** 17  **N at follow-up:**  **G1:** 13  **G2:** 16  **Age, mean years (range):**  **G1:** 36.4 (19, 45)  **G2:** 35.3 (29, 43)  **Race/ethnicity, n:**  White:  **G1:** 12  **G2:** 13  Black:  **G1:** 3  **G2:** 3  **BMI:**  NR  **Weight, mean pounds (range):**  **G1:**149.3 (108, 213)  **G2:** 164.7 (120, 130)  **Parity:**  **G1+G2:** All but 4 patients had one or more living children  **Contraception, n (%):**  Intrauterine device:  **G1+G2:** 7 (21)  Previous sterilization:  **G1+G2:** 6 (18)  Barrier methods:  **G1+G2:** 2 (15)  Partners with vasectomies or not sexually active:  **G1+G2:** 11  **Dysmenorrhea, n (%):**  Severe:  **G1+G2:** 10 (31)  Moderate:  **G1+G2:** 16 (50)  Dysmenorrheic:  **G1+G2:** 6 (18) | **Bleeding:**  MBL measured by alkaline hematin method, mean ml (SE):  **G1:** 141 (17.5)  **G2:** 141.8 (26.5)  **G1+G2**: 141.6 (15.9)  Number of bleeding days per cycle, mean (SE):  **G1+G2:** 6.3 (0.41)  Hemoglobin, median gm/dl:  **G1+G2:** 13.2  Hematocrit, median %:  **G1+G2:** 39.4  Ferritin, median ng/ml:  **G1+G2:** 16.0 | **Bleeding:**  MBL measured by alkaline hematin method, during treatment and placebo cycles, mean ml (SE):  **Ga:** 69.0 (6.34)  **Gb:** 135.6 (11.3)  MBL % change during treatment and placebo cycles from baseline, mean (SE):  **Ga:** -48.9 (3.7)  **Gb:** -9.2 (5.3)  **Ga** **vs. Gb:** p<0.0001  Number of bleeding days per cycle, mean (SE):  **Ga:** 4.8 (0.20)  **Gb:** 5.4 (0.18)  **Ga vs. BL:** p<0.0003  **Gb vs. BL:** p=NS  **Ga** **vs. Gb:** p<0.0003  Number of pads/tampons used, mean (SE):  **Ga:** 15.5 (0.9)  **Gb:** 27.6 (2.1)  **Ga vs. BL:** p<0.0001  **Gb vs. BL:** p=NS  **Ga** **vs. Gb:** p<0.0001  Hemoglobin, gm/dl, median:  **G1+G2:** 12.8  **G1+G2 vs. BL:** p=NS  Hematocrit, %, median:  **G1+G2:** 38.9  **G1+G2 vs. BL:** p=NS  Ferritin, ng/ml, median:  **G1+G2:** 14.8  **G1+G2 vs. BL:** p=NS  **Quality of life:**  NR  **Pain:**  Menstrual symptom severity assessed by patient rating,a mean score per cycle:  Dysmenorrhea:  **Ga:** 0.89  **Gb:** 1.38  **Ga** **vs. Gb:** p<0.006  Backache:  **Ga:** 0.20  **Gb:** 0.50  **Ga** **vs. Gb:** p<0.02  Headache:  **Ga:** 0.25  **Gb:** 0.63  **Ga** **vs. Gb:** p<0.002  Nausea:  **Ga:** 0.13  **Gb:** 0.17  **Ga** **vs. Gb:** p=NS  Vomiting:  **Ga:** 0.0  **Gb:** 0.05  **Ga** **vs. Gb:** p=NS  **Sexual function:**  NR  **Patient satisfaction:**  NR  **Fertility:**  NR  **Time to conception:**  NR  **Additional interventions:**  NR  **Adverse eventsb:**  Nausea/vomiting, n:  **Ga:** 4  **Gb:** NR  Epigastric distress, n:  **Ga:** 1  **Gb:** NR | **Overall Quality:**  Good  **Risk of bias:**  Randomization:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  Low  Other:  Low |

**Table Notes**: a Patient rated on a daily basis from none=0 to severe=3; b One patient discontinued the study because of gastric distress after one cycle of Meclomen. Two patients discontinued after screening phase for personal reasons.