**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 cyclesMedication 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 monthsTreatment phase: 2 months | **Inclusion criteria:** * Aged 16 to 42 years

History of menorrhagia >60 ml in one observation cycleNegative pregnancy test**Exclusion criteria:** Anovulatory cycles (proliferative endometrium)Histological evidence of pathological changes in the endometrium (hyperplasia or atypia)Extrauterine diseasePalpable leiomyomaKnown sensitivity to fenamatesAnticoagulant therapyThyroid dysfunctionHepatic diseaseRenal diseaseAbnormal 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:** 13Black:**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:** 13.2Hematocrit, median %:**G1+G2:** 39.4Ferritin, 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<0.0001Number 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<0.0003Number 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<0.0001Hemoglobin, gm/dl, median:**G1+G2:** 12.8**G1+G2 vs. BL:** p=NSHematocrit, %, median:**G1+G2:** 38.9**G1+G2 vs. BL:** p=NSFerritin, 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<0.006Backache:**Ga:** 0.20**Gb:** 0.50**Ga** **vs. Gb:** p<0.02Headache:**Ga:** 0.25**Gb:** 0.63**Ga** **vs. Gb:** p<0.002Nausea:**Ga:** 0.13**Gb:** 0.17**Ga** **vs. Gb:** p=NSVomiting:**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:** NREpigastric distress, n:**Ga:** 1**Gb:** NR | **Overall Quality:**Good**Risk of bias:** Randomization: LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:LowBlinding outcome assessment:LowIncomplete outcome reporting:LowOther: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.