**AUB KQ1 Evidence Table (Reference ID #935)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Preston et al., 1995**Country:**United Kingdom**Enrollment** **period:** NR**Intervention** **setting:** Hospitals and clinics**Funding:**Pharmacia**Author industry relationship disclosures:**NR**Study Design:** RCT, double blind, placebo controlled**Blinding:** Patients, clinicians | **Intervention:**Tranexamic acid1 gm, 4 times a day on days 1 to 4 and placebo on days 19 to 26**Comparator:**Placebo on days 1 to 4 and norethisterone5 mg twice per day on days 19 to 26Cycle 1: PlaceboCycle 2: PlaceboCycle 3: TreatmentCycle 4: Treatment**Groups:****G1:** Tranexamic acid**G2:** Norethisterone **Followup:**4 months | **Inclusion criteria:** * Aged 18 or older
* Cycle length 28 ± 7 days
* No hormone therapy within previous 3 months
* Not taking medication which might affect MBL
* No contraindication to either drug
* Normal renal function (serum creatinine <125 µmol/l)
* Normal pelvic examination
* Negative cervical cytology
* Menorrhagia (average MBL over 2 cycles >80 ml per cycle)

Regular cycle**Exclusion criteria:** See inclusion criteria**N at enrollment:** **G1:** 25**G2:** 21**N at followup:** **G1:** 25**G2:** 21**Age, mean years ± SD:****G1:** 40.6 ± 4.7**G2:** 39.3 ± 7.1**BMI:**NR**Weight, mean kg ± SD:****G1:** 71.2 ± 14.9**G2:** 63.5 ± 9.2**G1** **vs. G2:** p<0.048**Parity, n (%):**0:**G1:** 1 (4)**G2:** 1 (5)1:**G1:** 2 (8)**G2:** 3 (14)2:**G1:** 13 (52)**G2:** 10 (48)3:**G1:** 9 (36)**G2:** 6 (29)4:**G1:** 0**G2:** 1 (5)**Race/ethnicity:**NR | **Bleeding:**MBL measured using the alkaline hematin method at cycles 1 and 2 combined,a mean ml ± SD:**G1:** 175 ± 84**G2:** 173 ± 85Hemoglobin,b mean g/dl ± SD:**G1:** 12.3 ± 1.2**G2:** 12.0 ± 1.4Serum ferritin,b mean μg/l ± SD:**G1:** 11.2 ± 11.4**G2:** 8.9 ± 7.2Transferrin,b mean g/dl ± SD:**G1:** 3.68 ± 0.42**G2:** 3.64 ± 0.56 | **Bleeding:**MBL measured using the alkaline hematin method at cycles 3 and 4 combined,c mean ml ± SD:**G1:** 97 ± 89**G2:** 208 ± 135**G1 vs. BL:** p<0.0001**G2 vs. BL:** p=0.26**G1 vs.** **G2:** p<0.0001MBL estimated reduction from baseline, ml (95% CI):**G1:** 79 (62, 108)**G2:** -34 (-64, 2)**G1 vs.** **G2:** 113 (71, 155)MBL % change from baseline, mean (range):**G1:** -45 (-93, 23)**G2:** 20 (-62, 114) MBL < 80 ml per cycle, n: **G1:** 14/25**G2:** 2/21Hemoglobin, mean g/dl ± SD:**G1:** 12.9 ± 0.9**G2:** 12.6 ± 1.6Serum ferritin, mean μg/l ± SD: **G1:** 11.5 ± 6.0**G2:** 10.3 ± 6.8Transferrin, mean g/dl ± SD:**G1:** 3.34 ± 0.34**G2:** 4.74 ± 0.53**Quality of life:**General health, n (%):Better:**G1:** 12 (50)**G2:** 6 (30)Same/worse:**G1:** 12 (50)**G2:** 14 (70)Amount of flooding and leakage, n (%):Better:**G1:** 20 (83)**G2:** 9 (45)Same/worse:**G1:** 4 (17)**G2:** 11 (55)**G1 vs. G2:** p=0.008Limitation of social activities, n (%):Better:**G1:** 16 (67)**G2:** 9 (45)Same/worse:**G1:** 8 (33)**G2:** 11 (55)**Pain:**Abdominal pain, n (%):Better:**G1:** 9 (38)**G2:** 4 (20)Same/worse:**G1:** 15 (62)**G2:** 16 (80)**Sexual function, n (%):**Better:**G1:** 11 (46)**G2:** 3 (15)Same/worse:**G1:** 13 (54)**G2:** 17 (85)**G1 vs. G2:** p=0.029**Patient satisfaction:**Assessment of blood loss during treatment compared to placebo cycle, n (%):Better:**G1:** NR**G2:** NRSame/worse:**G1:** NR**G2:** NR**G1 vs. G2:** p=0.002d**Fertility:**NR**Time to conception:**NR**Additional interventions:**NR**Adverse events:**Dysmenorrhea, %:**G1:** 80**G2:** 85Headache, %:**G1:** 32**G2:** 48Gastrointestinal symptoms including diarrhea, nausea, vomiting, and dyspepsia, %:**G1:** 12**G2:** 33Weight gain, n:**G1:** 2**G2:** 0 | **Overall quality:**Fair**Risk of bias:** Randomization: LowAllocation concealment:LowSelective reporting:UnclearBlinding patients/personnel:LowBlinding outcome assessment:LowIncomplete outcome reporting:HighOther:Low |

**Table Notes:** a Data also given for cycles 1 and 2 separately; b Laboratory values are from the pre-placebo phase; c Data also given for cycles 3 and 4 separately; d Patients treated with tranexamic acid were significantly better than those treated with norethisterone.