**AUB KQ1 Evidence Table (Reference ID #631)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Davis et al., 2000**Country:**United States**Enrollment** **period:** May 1997 to October 1998**Intervention** **setting:** 16 sites**Funding:**Ortho-McNeil Pharmaceutical Corporation**Author industry relationship disclosures:**5/5 **Study Design:** RCT**Blinding:** Patients, investigators | **Intervention:**Days 1-7: 0.180 mg norgestimate/0.035 mg ethinyl estradiol;Days 8-14: 0.215 mg norgestimate/0.035 mg ethinyl estradiol; Days 15-21: 0.250 mg norgestimate/0.035 mg ethinyl estradiol; Days 22-28: inactive tablets **Comparator:**Days 1-28: placebo tablets**Groups:****G1:** Triphasic norgestimate/ethinyl estradiol**G2:** Placebo**Followup:**3 28-day treatment cycles (84 days) | **Inclusion criteria:** * Aged 15 to 50 years

Good general healthNot pregnant or nursingAt least 2-month history of menorrhagic, menometrorrhagic, oligomenorrheic or polymenorrheic dysfunctional uterine bleeding not attributed to systemic disease or structural pathology**Exclusion criteria:** History of endometrial ablation and undergone dilation and curettage within 90 days before screening visit**N at enrollment:** **G1:** 101 **G2:** 100 (ITT)**G1:** 97 **G2:** 95**N at followup:** **G1:** 60**G2:** 64**Age, mean years ± SD:****G1:** 29.8 ± 8.9**G2:** 29.3 ± 8.1**BMI:** NR**Weight, mean pounds ± SD:****G1:** 173.4 ± 55.9**G2:** 171.1 ± 48.5**Race, n (%):**White:**G1:** 73 (75.3)**G2:** 66 (69.5)Black:**G1:** 16 (16.5)**G2:** 22 (23.2)Asian:**G1:** 4 (4.1)**G2:** 1 (1.1)Other:**G1:** 4 (4.1)**G2:** 6 (6.3) | **Bleeding:**Duration of abnormal uterine bleeding, mean months ± SD:**G1:** 77.4 ± 73.5**G2:** 68.3 ± 71.2Duration of abnormal uterine bleeding, median months:**G1:** 67.6**G2:** 40.5Bleeding pattern history,a n (%):Metrorrhagia:**G1:** 23 (23.7)**G2:** 26 (27.4)Menometrorrhagia:**G1:** 29 (29.9)**G2:** 33 (34.7)Oligomenorrhea:**G1:** 54 (55.7)**G2:** 54 (56.8)Polymenorrhea:**G1:** 20 (20.6)**G2:** 20 (21.1)Hemoglobin, mean g/dl ± SD:**G1:** 12.7 ± 1.2**G2:** 12.85 ± 1.1**Quality of life:**SF-36 score,b mean:cPhysical functioning:**G1:** 88.60**G2:** 88.71Role functioning/physical:**G1:** 87.10**G2:** 89.12Bodily pain:**G1:** 70.99**G2:** 74.81General health:**G1:** 75.00**G2:** 77.36Vitality:**G1:** 57.04**G2:** 60.06Social functioning:**G1:** 84.01**G2:** 85.15Role functioning/emotional:**G1:** 78.85**G2:** 82.75Mental health:**G1:** 72.52**G2:** 75.29Reported health transition:**G1:** 41.13**G2:** 43.24Sexual functioning:**G1:** 19.27**G2:** 17.35 | Investigator-rated overall assessment of symptom resolution, %:Excellent:**G1:** 41.2**G2:** 10.5Good:**G1:** 26.8**G2:** 15.8Fair:**G1:** 13.4**G2:** 9.5No change:**G1:** 10.3**G2:** 46.3Worse:**G1:** 2.1**G2:** 2.1Unable to evaluate:**G1:** 6.2**G2:** 15.8**G1** **vs.** **G2:** p<0.001Subject-rated assessment of symptom improvement, %:Much improved:**G1:** 49.5**G2:** 19.8Improved:**G1:** 23.7**G2:** 19.8Slightly improved:**G1:** 14.0**G2:** 5.8No change:**G1:** 8.6**G2:** 47.7Worse:**G1:** 2.2**G2:** 3.5Don’t know:**G1:** 2.2**G2:** 3.5**G1** **vs.** **G2:** p<0.001**Quality of life:**SF-36b score,c mean change from baseline ± SD:d Physical functioning:**G1:** 4.19 ± 16.83**G2:** 0.47 ± 13.35**G1** **vs.** **G2:** p<0.001Role functioning/physical:**G1:** 1.61 ± 24.59**G2:** 1.18 ± 30.11**G1** **vs.** **G2:** p=0.160Bodily pain:**G1:** 4.45 ± 22.58**G2:** 0.15 ± 20.77**G1** **vs.** **G2:** p=0.896General health:**G1:** 1.58 ± 15.02**G2:** 1.12 ± 11.29**G1** **vs.** **G2:** p=0.265Vitality:**G1:** 6.18 ± 17.70**G2:** 3.94 ± 17.22**G1** **vs.** **G2:** p=0.410Social functioning:**G1:** 0.40 ± 20.06**G2:** -1.76 ± 21.58**G1** **vs.** **G2:** p=0.735Role functioning/emotional:**G1:** 6.09 ± 30.67**G2:** 2.75 ± 29.64**G1** **vs.** **G2:** p=0.694Mental health:**G1:** 4.52 ± 14.03**G2:** 1.65 ± 17.12**G1** **vs.** **G2:** p=0.935Reported health transition:**G1:** -4.03 ± 28.62**G2:** -4.41 ± 21.88**G1** **vs.** **G2:** p=0.109Sexual functioning:**G1:** -2.51 ± 22.75**G2:** -0.10 ± 26.05**G1** **vs.** **G2:** p=0.404**Patient satisfaction:****Fertility:**NR**Time to conception:**NR**Additional interventions:**NR**Adverse events:**Discontinued study prematurely, n (%):**G1:** 16 (15.8)**G2:** 19 (19)Discontinued due to adverse events, n:**G1:** 4**G2:** 3 | **Overall quality:** Good**Risk of bias:** Randomization: LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:LowBlinding outcome assessment:LowIncomplete outcome reporting:LowOther:Low |

**Table Notes:** Blood loss estimated from PBLAC Higham et al.; a Subjects could have more than one category of bleeding pattern history; b Medical Outcome Study, 36-item short-form health survey plus five items from the full set on sexual functioning; c Quality of life scores transformed to a 0-100 scale with a higher score indicating better quality of life, except for reported health transition and sexual functioning, for which a higher score indicates a lower quality; d Significance is computed using analysis of covariance with adjustment for baseline score, study centers, and interaction terms.