**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 health  Not pregnant or nursing  At 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 ± 71.2  Duration of abnormal uterine bleeding, median months:  **G1:** 67.6  **G2:** 40.5  Bleeding 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:c  Physical functioning:  **G1:** 88.60  **G2:** 88.71  Role functioning/physical:  **G1:** 87.10  **G2:** 89.12  Bodily pain:  **G1:** 70.99  **G2:** 74.81  General health:  **G1:** 75.00  **G2:** 77.36  Vitality:  **G1:** 57.04  **G2:** 60.06  Social functioning:  **G1:** 84.01  **G2:** 85.15  Role functioning/  emotional:  **G1:** 78.85  **G2:** 82.75  Mental health:  **G1:** 72.52  **G2:** 75.29  Reported health transition:  **G1:** 41.13  **G2:** 43.24  Sexual functioning:  **G1:** 19.27  **G2:** 17.35 | Investigator-rated overall assessment of symptom resolution, %:  Excellent:  **G1:** 41.2  **G2:** 10.5  Good:  **G1:** 26.8  **G2:** 15.8  Fair:  **G1:** 13.4  **G2:** 9.5  No change:  **G1:** 10.3  **G2:** 46.3  Worse:  **G1:** 2.1  **G2:** 2.1  Unable to evaluate:  **G1:** 6.2  **G2:** 15.8  **G1** **vs.** **G2:** p<0.001  Subject-rated assessment of symptom improvement, %:  Much improved:  **G1:** 49.5  **G2:** 19.8  Improved:  **G1:** 23.7  **G2:** 19.8  Slightly improved:  **G1:** 14.0  **G2:** 5.8  No change:  **G1:** 8.6  **G2:** 47.7  Worse:  **G1:** 2.2  **G2:** 3.5  Don’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<0.001  Role functioning/physical:  **G1:** 1.61 ± 24.59  **G2:** 1.18 ± 30.11  **G1** **vs.** **G2:** p=0.160  Bodily pain:  **G1:** 4.45 ± 22.58  **G2:** 0.15 ± 20.77  **G1** **vs.** **G2:** p=0.896  General health:  **G1:** 1.58 ± 15.02  **G2:** 1.12 ± 11.29  **G1** **vs.** **G2:** p=0.265  Vitality:  **G1:** 6.18 ± 17.70  **G2:** 3.94 ± 17.22  **G1** **vs.** **G2:** p=0.410  Social functioning:  **G1:** 0.40 ± 20.06  **G2:** -1.76 ± 21.58  **G1** **vs.** **G2:** p=0.735  Role functioning/emotional:  **G1:** 6.09 ± 30.67  **G2:** 2.75 ± 29.64  **G1** **vs.** **G2:** p=0.694  Mental health:  **G1:** 4.52 ± 14.03  **G2:** 1.65 ± 17.12  **G1** **vs.** **G2:** p=0.935  Reported health transition:  **G1:** -4.03 ± 28.62  **G2:** -4.41 ± 21.88  **G1** **vs.** **G2:** p=0.109  Sexual 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:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  Low  Other:  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.