**AUB KQ1 Evidence Table (Reference ID #123)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Endrikat et al., 2009**Country:**Canada**Enrollment** **period:** NR**Intervention** **setting:** 9 centers**Funding:**Bayer Schering Pharma AG, Berlin, Germany**Author industry relationship disclosures:**5/6**Study Design:** RCT**Blinding:** Open-label | **Intervention:**LNG-IUS 52 mg levonorgestrel released up to 20 µg per 24 hours inserted within 7 days of start of last menstrual period for 12 months**Comparator:**One tablet daily for 12 months of COC containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol for days 1-21 and placebo tablet for days 22-28 **Groups:****G1:** LNG-IUS**G2:** COC**Followup:**12 months | **Inclusion criteria:** Aged ≥30 yearsHealthy * Diagnosis of idiopathic menorrhagia assessed by MBL score ≥100 on PBLAC for two consecutive cycles

Normal or only slightly enlarged uterus**Exclusion criteria:** Contraindications for LNG-IUS and COC useMetabolic and endocrine diseasesDiagnostically unclassified genital bleedingHistory of liver or vascular diseaseConcomitant use of medications that could influence study objective, including: sex steroids; tranexamic acid; NSAIDs; platelet aggregation inhibitors; anticoagulants; and drugs known to induce or inhibit liver enzymesIntramural or subserous fibroids of mean diameter ≥4 cm or submucous fibroidsAdenomyosis or endometrial abnormalities (e.g., polyps or hyperplasia)Perimenopausal **N at enrollment:** **G1:** 20**G2:** 19**N at followup:** **G1:** 17**G2:** 12**Time since start of menorrhagia, mean years ± SD:****G1:** 10.0 ± 8.23**G2:** 6.1 ± 4.4**Age, mean years ± SD:****G1:** 41.8 ± 4.3**G2:** 42.4 ± 4.4**BMI, mean kg/m2 ± SD****G1:** 24.3 ± 1.9**G2:** 22.6 ± 2.3**Births, n (%)**0:**G1:** 3 (15.0)**G2:** 3 (15.8)1:**G1:** 6 (30.0)**G2:** 4 (21.1)2:**G1:** 6 (30.0)**G2:** 10 (52.6)≥3:**G1:** 5 (25.0)**G2:** 2 (10.5)**Race/ethnicity:**NR | **Bleeding:**MBL measured by PBLAC score, median:**G1:** 228**G2:** 290Hemoglobin,a mean g/L:**G1:** 126**G2:** 125 | **Bleeding:**MBL measured by PBLAC score at 12 months, median:**G1:** 13 **G2:** 72 **G1** **vs.** **BL:** p<0.001**G2** **vs.** **BL:** p<0.001**G1** **vs.** **G2:** p=0.002MBL measured by PBLAC score at 12 months, estimate for median difference (95% CI):**G1** **vs.** **G2:** -62 (-89, -18)MBL measured by PBLAC score at 12 months, mean % change:**G1:** -83**G2:** -68Treatment success,b n (%):**G1:** 16/20 (80.0)**G2:** 7/19 (36.8)**G1 vs. G2:** p<0.009Hemoglobin at 12 months, mean g/L:**G1:** 134**G2:** 136Hemoglobin at 12 months, baseline-adjusted mean g/L change: **G1:** +8.6**G2:** +9.6**G1 vs.** **G2:** p=0.711Hemoglobin, estimate for mean difference (95% CI):**G1 vs.** **G2:** -0.99 (-6.43, 4.45)**Quality of life:**Menorrhagia severity scorec:6 months:**G1:** NR**G2:** NR**G1 vs.** **G2:** p=0.04512 months:**G1:** NR**G2:** NR**G1 vs.** **G2:** p=NSMenorrhagia severity score, estimated mean % difference at 6 months (95% CI): **G1 vs. G2:** -6.37d (-12.61, -0.14)**Pain:**NR**Sexual function:**NR**Patient satisfaction:**NR**Fertility:**NR**Time to conception:**NR**Additional interventions:**NR**Adverse events:**Discontinued study (reasons were intermenstrual bleeding, menstrual disorder, and headache), n: **G1:** 1**G2:** 5 | **Overall quality:** Poor**Risk of bias:** Randomization: LowAllocation concealment:HighSelective reporting:LowBlinding patients/personnel:HighBlinding outcome assessment:UnclearIncomplete outcome reporting:LowOther:High |

**Table Notes**: a Hemoglobin analyzed in the sub-population who had not used iron supplements during the study. Results were similar to whole study population (data not shown); b Treatment success defined as MBL score < 100 at 12 months; treatment failure recorded if MBL score ≥ 100 or if treatment was discontinued; c Assessed by condition specific questionnaire (see: Ruta et al.) but scores only displayed graphically; d Menorrhagia severity scores significantly lower (better quality of life) in G1 compared to G2 at 6 months.