**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 years  Healthy   * 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 use  Metabolic and endocrine diseases  Diagnostically unclassified genital bleeding  History of liver or vascular disease  Concomitant 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 enzymes  Intramural or subserous fibroids of mean diameter ≥4 cm or submucous fibroids  Adenomyosis 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:** 290  Hemoglobin,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=0.002  MBL 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:** -68  Treatment success,b n (%):  **G1:** 16/20 (80.0)  **G2:** 7/19 (36.8)  **G1 vs. G2:** p<0.009  Hemoglobin at 12 months, mean g/L:  **G1:** 134  **G2:** 136  Hemoglobin at 12 months, baseline-adjusted mean g/L change:  **G1:** +8.6  **G2:** +9.6  **G1 vs.** **G2:** p=0.711  Hemoglobin, 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=0.045  12 months:  **G1:** NR  **G2:** NR  **G1 vs.** **G2:** p=NS  Menorrhagia 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:  Low  Allocation concealment:  High  Selective reporting:  Low  Blinding patients/personnel:  High  Blinding outcome assessment:  Unclear  Incomplete outcome reporting:  Low  Other:  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.