**Trial 2012: Surgical Procedures (Hysterectomy)**

### **The effect of hysterectomy or levonorgestrel-releasing intrauterine system on premenstrual symptoms in women treated for menorrhagia: secondary analysis of a randomized controlled trial**

**Link:** <https://pubmed.ncbi.nlm.nih.gov/22168810/>

**Year published:** 2012

**Pubmed classification:** Randomised Controlled Trial.

**Further trial: *information****Secondary* analysis.

**Objective:** To study the effect of hysterectomy or levonorgestrel-releasing intrauterine system (LNG-IUS) on premenstrual symptoms in women treated for menorrhagia.

**Randomised?** Yes.

**Placebo?** No.

**Participant information:** A cohort of 236 women in Finland, aged 35-49 years (mean 43 years) referred for menorrhagia between 1994 and 1997. The women were not diagnosed with premenstrual syndrome.

**Trial length:** Assessments after the treatment at 6 months, 12 months, and 5 years after the randomisation.

**Drug and dosage:** Hysterectomy (117); or LNG-IUS (119).

**Measuring scales:** The occurrence of premenstrual symptoms evaluated by questionnaires at baseline and at follow-up visits 6 and 12 months after the treatment and 5 years after the randomization.

**Methodology further information:** Analyses were performed using the intention-to-treat and actual treatment principles. Women using estrogen therapy and women who underwent bilateral salpingo-oophorectomy were excluded from the analyses.

**Efficacy outcomes:** Premenstrual symptoms decreased significantly in both groups by six months (p≤0.028) without significant differences between the groups, except that in the LNG-IUS group the decrease of breast tenderness was seen first by 12 months (p=0.048).

Even though 42% of the women assigned to treatment with LNG-IUS were hysterectomized during the follow-up period, the results of intention-to-treat and actual treatment analyses were comparable.

**Conclusion:** Both hysterectomy and LNG-IUS seem to alleviate premenstrual symptoms of women treated for menorrhagia, while the effect of these treatments on premenstrual syndrome remains unsettled.

**Trial 2011: Surgical Procedures (Novasure)**

**Improved premenstrual syndrome symptoms after NovaSure endometrial ablation**

**Link:** <https://pubmed.ncbi.nlm.nih.gov/21872168/>

**Year published**: 2011

**Trial information:** Prospective, single-arm cohort study.

**Objective:** To evaluate the change in premenstrual syndrome (PMS) symptoms in women with heavy periods who underwent endometrial ablation.

**Participant information:** 36 women with heavy periods who were to undergo endometrial ablation, had PMS symptoms and completed all surveys at baseline and follow-up. The mean age was 41.4 years, with a mean body mass index of 26.7. Most (27/36, 75%) had failed hormonal management.

**Trial length:** Follow-up surveys at 4 to 6 months.

**Measuring scales**: A brief baseline survey was done to evaluate menstrual bleeding and baseline PMS symptoms, and two 30-day prospective validated measures of PMS were used. Follow-up surveys were sent at 4 to 6 months and included both the brief survey questions and the validated measures of PMS (Daily Symptoms Report and Daily Record of Severity of Symptoms).

**Efficacy outcomes:** All measures of PMS showed significant improvement after endometrial ablation. Self-rating of PMS symptoms on a scale of 0 (none) to 10 (severe) improved from a baseline of 7.4 to a follow-up rating of 3.2 (p <.05).

The vast majority of women (35/36, 97%) reported improvement in PMS after undergoing endometrial ablation. Both validated measures of PMS, Daily Symptoms Report and Daily Record of Severity of Symptoms, showed statistically significant improvement in PMS symptoms.

**Conclusion:** Women with heavy menses and associated PMS symptoms who undergo NovaSure endometrial ablation showed improvement in PMS symptoms, as well as reduced menstrual bleeding.

**Trial 2004: Surgical Procedures (Hysterectomy and Oophorectomy)**

**Hysterectomy and bilateral oophorectomy for severe premenstrual syndrome**

**Link:** https://pubmed.ncbi.nlm.nih.gov/15229203/

**Year published:** 2004

**Objective:** To evaluate the effectiveness and patient satisfaction with total abdominal hysterectomy/bilateral salpingo-oophorectomy (TAH/BSO) in PMS sufferers; and assessing the post-operative HRT continuation.

**Participant information:** 47 women undergoing TAH/BSO for severe PMS (1994-2000). Median age was 42 years (interquartile range 39.8-46.6) at the time of surgery. They had suffered with PMS for a mean of 9.68 years (SD 6.8) and received treatment for a mean of 3.57 years (SD 2.0) prior to referral to a gynaecologist. 52% were treated with estradiol patches and 48% with estradiol implants prior to TAH/BSO.

**Measuring scales:** Interviews; responses recorded by structured questionnaire.

**Efficacy outcomes:** 96% of women were 'satisfied' or 'very satisfied' with TAH/BSO, and 93.6% declared complete resolution of their cyclical symptoms; 93.6% were continuing with HRT, usually by implants of estradiol and testosterone, for a mean duration of 3.8 years (SD 1.86) post-operatively.

**Conclusion:** Despite few reports of TAH/BSO as a treatment for severe PMS, we have found surgery, coupled with appropriate HRT, to be an extremely effective and well-accepted permanent cure for PMS.