

# Study of Understanding NAEH - Treatment Efficacy of Levonorgestrel – IUS in Women Electing Non-Surgical Options

**A phase 3 investigational study evaluating the efficacy and safety of 52mg levonorgestrel-releasing intrauterine system Mirena® for the treatment of nonatypical endometrial hyperplasia (NAEH) in women**

- Study design:** Open label, randomized (2:1), parallel group, multi-center study
- Patient population:** Nulliparous and parous women (≥18 years of age) independent of their menopausal status
- Patient enrollment:** 207 (estimated)
- Study centers:** 90 located in the United States, Canada, and China
- Study duration:** Patient: 10 months; Site: 18 months
- Study site visit:** Up to 5 visits
- Assessments:** Transvaginal ultrasound, hysteroscopy, endometrial biopsy

- Inclusion Criteria**
- Post-menarchal women (≥18 years) at the time of signing the informed consent
  - Women with histologically confirmed NAEH independent of their parity or menopausal status

- Exclusion Criteria**
- Any diseases or conditions that might interfere with the conduct of the study or the interpretation of the results
  - Congenital or acquired uterine or cervical anomaly including fibroids, or cervical stenosis that in the opinion of the investigator, would interfere with insertion and/or retention of the intrauterine system (ie, if they distort the uterine cavity)
  - Use of any long-acting injectable sex-hormone preparations within 6 months prior to the start of study intervention, and/or short-acting hormonal medication within 6 weeks prior to the start of study intervention
  - Pregnancy
  - Participants with either known family or personal history of genetic predisposition to uterine, ovarian, or colorectal cancers (eg, Lynch syndrome)

**For more information about this trial, please contact:** [luba.soskin@bayer.com](mailto:luba.soskin@bayer.com)

**For general inquiries, please contact medical affairs:** <https://askmed.bayer.com/>

**ClinicalTrials.gov identifier:** NCT06904274

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The clinical trial presented here is being investigated for uses that have not been approved by the US Food and Drug Administration (FDA), European Medicines Agency (EMA), or other health authorities.

This information is presented only for purposes of providing a general overview of clinical trials and should not be construed as a recommendation for use of any product for unapproved uses.

References:  
 1. Bayer AG; 2025. <https://www.bayer.com/en/us/news-stories/treatment-of-nonatypical-endometrial-hyperplasia>  
 2. NCT0690274. Bayer; 2026. <https://clinicaltrials.gov/study/NCT06904274>

## Study Purpose

To evaluate the proportion of women with complete resolution of NAEH treated with Mirena or oral medroxyprogesterone acetate for 6 months

## Arms and Interventions

Mirena	Medroxyprogesterone acetate
(Levonorgestrel) Experimental treatment	(Oral progestin) Active comparator
<ul style="list-style-type: none"> <li>Mirena will be inserted into the participant's uterus by the investigator on day 1</li> <li>Mirena will be removed by the investigator at visit 4 (after 6 months), or if a participant discontinues her study participation prematurely</li> </ul>	<ul style="list-style-type: none"> <li>Participants will receive oral progestin 10 mg once daily, preferably always at the same time of the day, until visit 4 (after 6 months)</li> </ul>

## Primary Outcome Measure

**Proportion of participants with complete resolution (CR) of NAEH**

- CR will be evaluated as benign endometrium
- Assessed at 6 months

## Secondary Outcome Measures

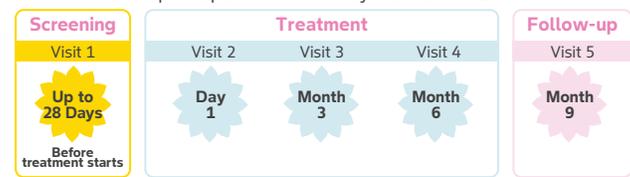
- Recurrence of NAEH after CR**
  - Recurrence of NAEH on 3 months treatment-free after CR at 6 months
  - Assessed at 3-month follow-up after 6 months treatment
- Progression after CR**
  - Endometrial hyperplasia with atypia or endometrial cancer after 3-month treatment-free follow-up after CR at 6 months
  - Assessed at 3-month follow-up after 6 months treatment
- Proportion of participants having hysterectomy**
  - Assessed during treatment and 3-month follow-up
- Diagnosis of "benign endometrium"**
  - Assessed at 6 months of treatment followed by 3-month treatment-free follow-up
- Number of participants with adverse events**
  - Assessed from the signing of the informed consent form up to 3 months after the last dose of study intervention

## Estimated Study Timeline



## Visit Schedule

Patient's participation in the study will last for 10 months



Intended for healthcare professionals only