

# Investigating Ovulation Inhibition for Use as a Contraceptive

NCT07365904

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Mylan Pharmaceuticals Inc
<b>Enrollment</b>	60 participants

## Key Eligibility Criteria

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### Inclusion (7)

- \. Healthy, post-menarcheal and premenopausal women of age 18 to 35 years (inclusive) at screening examination.
- \. BMI  $\leq 18.0$  kg/m<sup>2</sup> at screening examination. 3. Participants must be in good physical and mental health as determined by vital signs, medical history, and physical and gynecological examination, as assessed by the investigator.
- \. Written informed consent, after having been informed about benefits and potential risks of the clinical trial, as well as details of the insurance taken out to cover the participant participating in the clinical trial.
- \. Status at least 3 months after a delivery, abortion, and stopping lactation, if applicable, before screening.
- \. Has regular menstrual cycles that are between 21 and 35 days in duration as reported by the participant during anamnesis, with an intact uterus and ovaries. If the participant uses hormonal birth control at screening, historic data should be used to evaluate this criterion.

... and 2 more (see full listing online)

### Exclusion (13)

- \. Known hypersensitivity or intolerance to any ingredient of the investigational product.
- \. History or presence of dermal sensitivity to medicated patches or to topical applications including bandages, surgical tape.
- \. Pregnancy or a positive serum beta human chorionic gonadotropin (<sup>2</sup>hCG) pregnancy test at screening.
- \. Clinically relevant abnormal findings from serum biochemistry and hematology and HBsAG/ Hepatitis C virus/ human immunodeficiency virus (HIV) serology as evaluated by the investigator 5. ASAT (aspartate-aminotransferase)  $> 20$  % upper limit of normal (ULN), ALAT (alanine-aminotransferase)  $> 10$  % ULN, bilirubin  $> 20$ % ULN (except in case of existing Morbus Gilbert-Meulengracht deduced from anamnesis/medical history) and creatinine  $> 0.1$  mg/dL ULN (limit of  $> 0.1$  mg/dL corresponds to  $> 9$   $\mu$ mol/l ULN).
- \. Use of a non-hormonal intra-uterine device within the pre-treatment cycle or any hormonal contraception as follows:

... and 8 more (see full listing online)

## Locations (1 total)

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dinox GmbH, Berlin, Germany