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Acceptability and satisfaction of Dienogest in the treatment of patients with symptomatic endometriosis

Submission date
07/03/2024

Recruitment status
No longer recruiting

Registration date
13/03/2024

Overall study status
Completed

Last Edited
27/01/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
To establish the efficacy of 2 mg dienogest per day over 6 months in an Asian population for the management of endometriosis.

Who can participate?
Any patients 18 years up to 45 years with endometriosis

What does the study involve?
A hormonal treatment with 2 mg Dienogest for patients with endometriosis; this over a time of 6 months. A clinical evaluation and the recording of side effects will be performed at the months 3 and 6 of the treatment.

What are the possible benefits and risks of participating?
Benefits: A significant improvement in the endometriosis associated pain. Side effects: possible clinical signs of hypoestrogenimn like hot flushes.

Where is the study run from?
Exeltis Thailand

When is the study starting and how long is it expected to run for?
September 2023 to October 2025

Who is funding the study?
Exeltis Thailand

Who is the main contact?
Asst. Prof. Ammarin Suwan

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Pedro Antonio Regidor

ORCID ID
https://orcid.org/0000-0002-9551-2847

Contact details
Adalperostr. 84
Ismaning
Germany
85737
+49 1738938132
pedro-antonio.regidor@exeltis.com

Additional identifiers

Study information

Scientific Title
Acceptability and satisfaction of Dienogest in the treatment of patients with symptomatic endometriosis

Acronym
Endogest

Study objectives
To investigate acceptability and satisfaction of Dienogest in the treatment of patients with symptomatic endometriosis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/09/2023, Institutional Review Board, Faculty of Medicine, Chulalongkorn University (1873 Rama 4 Road 10330 Bangkok Thailand, Bangkok, 10330, Thailand; +662 256-4493; medchulairb@chula.ac.th), ref: COA No. 1267/2023

Primary study design
Observational

Study design
Observational prospective study

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Endometriosis

Interventions
An observational prospective study will be conducted at King Chulalongkorn Memorial Hospital. The expected duration of subject participation is approximately 6 months.
Subjects visiting gynaecology complaining about pelvic pain that the investigator suspect related to endometriosis will be identified. Thereafter, the investigator or assignee will provide information about the trial. If the patient agrees to participate, informed consent will be written. Screening procedures and baseline assessment will then take place.
Treatment of endometriosis with Dienogest 2mg per day
Subjects will be followed up at the 3rd and 6th month after taking dienogest for endometriosis treatment at Gynecology Outpatient Clinic, King Chulalongkorn Memorial Hospital

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dienogest

Primary outcome(s)
Endometriosis-associated pain symptoms after 3 months and 6 months of Dienogest treatment measured using a questionnaire

Key secondary outcome(s)
Tolerability and safety aspects after the use of Dienogest for 6 months measured using routine controls

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Female patients, age ≥ 18 and ≤ 45 years.
2. Present at least one classical symptom of endometriosis associated pain including dysmenorrhea, dyspareunia, chronic pelvic pain, dysdefecation without any other pathology by taking a history or physical examination plus Visual Analogue Scale (VAS) ≥ 4
3. Decision taken by the physician to prescribe Dienogest 2 mg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
62

Key exclusion criteria
1. Current Body mass Index (BMI) > 30 kg/m²
2. Patients with severe acute or chronic diseases (e.g. pancreatitis, hypertriglyceridemia, liver disease, benign or malignant liver tumor, malignant sex-hormone dependent diseases of genitals or breasts)
3. Intake of herbal medicines or medicines which induce microsomal enzymes, especially cytochrome-P450-enzyme, e.g. Phenytoin, Phenobarbital, Primidon Bosentan, Carbamazepine, Rifampicin, Topiramate, Felbamat, Griseofulvin, a few HIV protease inhibitors (e.g. Ritonavir), and non-nucleosidic Reverse-Transcriptase-Inhibitors (e.g. Efavirenz) as well as preparations of Aaron´s beard.
4. History of cardiovascular events
5. Advanced hypertension or diabetes
6. Known hypersensitivity to components of Dienogest
7. Undiagnosed abnormal vaginal bleeding
8. Use of drugs containing Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir during and two weeks before start of the study
9. Patients using intrauterine devices (IUD) or intrauterine systems (IUS)
10. Pregnancy
11. Breast feeding
12. Patients who are postmenopausal
13. Patients switching from a GnRH agonist, hormonal contraception, or progestin treatment within 3 months
14. Participation in any other trial 30 days before starting to use Dienogest

Date of first enrolment
01/03/2024

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
Thailand

Study participating centre

Chulalongkorn University
Division of Obstetrics and Gynecology, Faculty of Medicine
Rama IV Road, Pathumwan district
Bangkok
Thailand
10330

Sponsor information

Organisation
Exeltis Thailand

Funder(s)

Funder type
Industry

Funder Name
Exeltis Thailand

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/01/2026	27/01/2026	Yes	No
Protocol file	version 1.2		11/03/2024	No	No