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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
07/03/2024		[X] Protocol		
Registration date	Overall study status Completed Condition category Urological and Genital Diseases	Statistical analysis plan		
13/03/2024		Results		
Last Edited		Individual participant data		
11/03/2024		Record updated in last year		

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

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

Study design

Observational prospective study

Primary study design

Observational

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 \geq 18 and \leq 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

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

The current data sharing plans for this study are unknown and will be available at a later date

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.2		11/03/2024	No	No