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

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

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

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

Secondary outcome measures

Tolerability and safety aspects after the use of Dienogest for 6 months measured using routine controls

Overall study start date
28/09/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
65

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
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Sponsor information

Organisation
Exeltis Thailand

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Exeltis Thailand

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2025

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?
Protocol file	version 1.2		11/03/2024	No	No