

# Diphereline Post Marketing Surveillance Study

**First published:** 17/08/2020

**Last updated:** 01/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36791

---

### Study ID

36792

---

### DARWIN EU® study

No

---

### Study countries

 Korea, Democratic People's Republic of

---

### Study description

To assess the efficacy and safety of Diphereline in treating Endometriosis and Fibromyoma.

---

### Study status

Finalised

# Research institutions and networks

## Institutions

Ipsen Pharma

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 12 centres are involved in the study

## Contact details

### Study institution contact

Medical Director [clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

Study contact

[clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

### Primary lead investigator

Medical Director

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 20/05/2005

Actual: 20/05/2005

---

## **Study start date**

Planned: 31/05/2005

Actual: 20/05/2005

---

## **Data analysis start date**

Planned: 31/03/2006

Actual: 30/12/2005

---

## **Date of final study report**

Planned: 31/03/2006

Actual: 15/12/2014

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Ipsen

# Regulatory

## **Was the study required by a regulatory body?**

No

---

## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Combined primary data collection and secondary use of data

---

**Main study objective:**

The objective of the study was to assess the safety and efficacy of Diphereline 3.75 mg in gynaecology use such as Endometriosis and Fibromyoma

## Study Design

## **Non-interventional study design**

Other

---

## **Non-interventional study design, other**

Open, non-comparative, multi-center, phase IV study

# Study drug and medical condition

## **Medicinal product name, other**

Diphereline 3.75mg

---

## **Study drug International non-proprietary name (INN) or common name**

TRIPTORELIN

---

## **Anatomical Therapeutic Chemical (ATC) code**

(L02AE04) triptorelin

triptorelin

---

## **Medical condition to be studied**

Endometriosis

---

## **Additional medical condition(s)**

Fibromyoma

# Population studied

## **Short description of the study population**

Inclusion criteria:

- Patients who suffer from Endometriosis or Fibromyoma
- Patients who need GnRH agonist after laparoscopy diagnosis of Endometriosis
- Patients who need GnRH agonist to facilitate or modify a Fibromyoma related surgical technique

Exclusion criteria:

- Pregnant or breast-feeding women
  - Hypersensitivity to GnRH analogues or to one of its excipients
  - Patients who were recently (< 6 months) administered triptorelin or another GnRH analogue
- 

### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- 

### **Estimated number of subjects**

245

## Study design details

### **Outcomes**

Efficacy assessment: physical examination and symptoms report, hormonal responses, overall evaluation according to the criteria from 1-notably improved until 5 worsened and 6 not available. Safety assessment: AEs

---

### **Data analysis plan**

The proportions of patients with all levels of improvement were determined. All proportions were presented with a corresponding 95% confidence interval. Safety was evaluated in relation to the number of AE events and the number of cases with abnormal results in relevant laboratory tests.

## Documents

## Study results

[a3852014118-synopsis\\_Redacted.pdf](#) (20.65 KB)

---

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

---

### Data sources (types), other

Simple Case Record Form

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No