Diphereline Post Marketing Surveillance Study

First published: 17/08/2020

Last updated: 01/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36792

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

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Institution

Multiple centres: 12 centres are involved in the study

Contact details

Study institution contact

Medical Director

Study contact

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

Name of medicine, 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

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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

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