Study on the fertility of women treated with triptorelin for precocious puberty in their childhood (PREFER)

First published: 06/11/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS7895

Study ID

30165

DARWIN EU® study

No

Study countries

☐ France

Study description

PREFER is a longitudinal, prospective, descriptive, non-comparative epidemiological study of women treated during childhood for precocious puberty with the Gonadotrophin Releasing Hormone (GnRH) analogue, triptorelin. The study examined the fertility of these women during the 2 years prior to inclusion and during the follow-up period (1 year). The women were sent questionnaires by post once their informed consent forms had been returned to the paediatric service that treated them for precocious puberty during their childhood. Only clinical pregnancies should be considered, i.e. confirmed by a menstrual delay greater than 15 days and ultrasound evidence (at least a gestational sac). The fertility of these women should be compared to data in the literature for women of comparable age. The study objective was to determine whether women treated during childhood for precocious puberty with triptorelin have the same one-year pregnancy rates than couples trying to conceive, i.e. approximately 85% according to numerous publications 12-15. It was planned to also compare the results of the PREFER study to the fertility of French couples and their Waiting Time to Pregnancy (WTP), based on various socio-economic and demographic data generated by a survey on the fertility in France (Génération et Genre), conducted at the end of 2005 jointly by INED (Institut National d'Etudes Démographiques) and INSEE (Institut National de la Statistique et des Etudes Economiques) on a sample of 10,000 people representative of the French population.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 23 centres are involved in the study

Contact details

Study institution contact

Ipsen Medical Director clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2007

Actual: 01/01/2007

Study start date
Planned: 01/02/2007

Actual: 01/02/2007

Date of final study report
Planned: 31/12/2010

Actual: 05/09/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IPSEN Pharma

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluation of fertility of women treated during their childhood for precocious puberty with triptorelin

Data collection methods:

Primary data collection

Main study objective:

To analyse the fertility of women treated during childhood for precocious puberty with triptorelin.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal, prospective, descriptive, non-comparative epidemiological study

Population studied

Short description of the study population

Women treated during childhood for precocious puberty with the Gonadotrophin Releasing Hormone (GnRH) analogue, triptorelin.

Age groups

Adults (18 to < 46 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

504

Study design details

Outcomes

Fertility, • progress and outcome of the pregnancies, including the condition of the child at birth. • ovarian function and biometry of the women.• influence on fertility of the age at the time of diagnosis, etiology of precocious puberty, and treatment modalities. • socio-economic consequences of this condition (academic level, living conditions, occupation).

Data analysis plan

• Description of the population included• Checking for biases by comparing the major data of the included patients with those of patients who could not be found or refused to participate in the study (data processing being totally anonymous)• Analysis of risk factors for the primary and secondary endpoints • Patient characteristics: age, age at diagnosis, seriousness of precocious puberty, weight, etc. • Characteristics of the treatment for precocious puberty:

duration, doses, concomitant treatments in addition to triptorelin, e.g. medroxyprogesterone or cyproterones• Comparison of the pregnancy rate observed in women trying to conceive with the theoretical rate of the general population (85%)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown