Post-marketing Observational Study to Characterize the Safety and Effectiveness Profile of Orgalutran® in Chinese Women Undergoing Controlled Ovarian Hyperstimulation for Assisted Reproduction Techniques (MK-8761-050)

First published: 31/03/2015

Last updated: 11/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22133

EU PAS number

EUPAS8737

Study ID

22133

DARWIN EU® study

No

Study countries

☐ China

Study description

This is a post-marketing observational study of Orgalutran in Chinese women undergoing controlled overian hyperstimulation during an assisted reproductive technology protocol. The primary objective is to characterize the safety and effectiveness of Orgalutran in the Chinese population in the setting of routine clinical practice in China.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Study contact

datasharing@organon.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/10/2014

Study start date

Planned: 30/04/2015

Actual: 28/04/2015

Data analysis start date

Planned: 13/06/2017

Actual: 06/06/2017

Date of final study report
Planned: 20/12/2017

Actual: 05/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Regulatory

Was the study required by a regulatory body?

Yes

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective is to characterize the safety and effectiveness of Orgalutran in the Chinese population in the setting of routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ORGALUTRAN

Medical condition to be studied

Infertility

Infertility female

Population studied

Short description of the study population

Chinese women undergoing controlled overian hyperstimulation during an assisted reproductive technology receiving Orgalutran® for routine clinical practice in China.

Age groups

Adults (18 to < 46 years)

Special population of interest

Other

Special population of interest, other

Infertile female patients

Estimated number of subjects

1000

Study design details

Outcomes

Number of participants experiencing AEs and discontinuing study drug due to AEs, Serum concentration of LH at baseline, Days and total dosage of FSH administered, Number and size distribution of follicles, Number oocyte

retrieved, Number embryos surviving at day of ET/embryos transferred, Proportion of women with positive pregnancy test/vital pregnancy, Proportion of women with a live-born baby.

Data analysis plan

Safety endpoints will be summarized by count, point estimate and corresponding 95% confidence interval if applicable. The effective measures and subsequent clinical outcomes will be summarized by count, point estimate with standard deviation if applicable, and may be presented by age categories if applicable. Newborn measures will be summarized by count, point estimate with standard deviation, if applicable.

Documents

Study results

MK 8761-050 Synopsis Final Redaction .pdf(1.55 MB)

Data management

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

No