# 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.

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

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

**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

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**Study start date**

Planned: 30/04/2015

Actual: 28/04/2015

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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**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