

A Post-Marketing Observational Study of Implanon® Radiopaque among Chinese Women Aged 18 and Older Requesting Contraception (MK-8415-038)

First published: 27/01/2016

Last updated: 11/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS11131

Study ID

47862

DARWIN EU® study

No

Study countries

 China

Study description

This is a post-marketing observational study intended to evaluate participant and physician satisfaction, serious adverse events (SAEs), drug related adverse events (AEs) including topical AEs as well as overall contraceptive effectiveness in routine clinical practice. The primary objective is to evaluate the overall safety profile of Implanon® Radiopaque.


Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

 United States

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Last updated: 08/07/2025

Institution

Pharmaceutical company

Merck Sharp & Dohme (China) Ltd. Level 7, Tower E3, The Towers, Oriental, Beijing, 100738 China

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/11/2014

Study start date

Planned: 18/03/2016

Actual: 24/03/2016

Data analysis start date

Planned: 15/07/2021

Actual: 27/07/2021

Date of interim report, if expected

Planned: 09/03/2018

Date of final study report

Planned: 28/04/2022

Actual: 06/06/2022

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:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective is to evaluate the overall safety profile of Implanon® Radiopaque.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Postmarketing observational study

Study drug and medical condition

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

Women \geq 18 years of age at the time of screening requesting contraception at approximately 50 sites throughout China. The identification of eligible subjects was to be based on standard clinical practice and the product labeling. All

investigators were to be trained to insert Implanon® Radiopaque. Subjects who were willing to join this survey and sign the ICF were to be enrolled and followed, and the decision of the subject to use the Implanon® Radiopaque would have been made prior to the decision to be involved in the observational study.

Inclusion Criteria

All inclusion criteria were reviewed by the investigator or qualified designee to ensure that the subject qualifies for the study.

- Women ≥ 18 years of age at the time of screening requesting contraception;
 - Capable to answer the questionnaire;
 - Decided to use Implanon® Radiopaque for contraception;
 - Willing to participate in the survey and give informed consent in writing.
-

Age groups

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

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

1900

Study design details

Outcomes

The participant proportion of (1) drug related AEs, (2) SAEs, (3) discontinuation due to drug-related AE or SAE. (1) To evaluate the topical safety profile of IMPLANON, (2) to assess participant and physician satisfaction with IMPLANON, (3) to estimate the overall contraceptive effectiveness of IMPLANON.

Data analysis plan

Summary statistics of socio-demographic and clinical characteristics of participants on Implanon® Radiopaque treatment will be tabulated. Safety endpoints will be summarized by count, point estimate and corresponding 95% confidence interval (CI).

Documents

Study results

[MK-8415-038-02-CSR_final redaction.pdf](#) (1.54 MB)

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

No