Nexplanon Observational Risk Assessment Study (NORA)

First published: 04/11/2011

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1999

Study ID

31766

DARWIN EU® study

No

Study countries

☐ United States

Study description

Nexplanon is a subdermal contraceptive implant containing the progestogen etonogestrel and providing continuous contraceptive protection for three years. In contrast to its predecessor, Implanon, Nexplanon (etonogestrel radiopaque

implant) contains barium sulfate and has a new Next Generation Implanon Applicator (NGIA) application device. The barium sulfate will extend the diagnostic modalities for localization of the implant by making it radiopaque and hence visible via X-ray imaging and X-ray Computerized Tomography (CT). It is anticipated that the NGIA should further facilitate correct insertion of the implant in the subdermal layer of the skin. The NORA study is designed to collect information on insertion-, localization- and removal-related events. The study is being conducted as a post-approval regulatory commitment for the FDA and includes a single cohort of US women using Nexplanon. The objective of the study is to characterize the frequency of specific insertion-, localization- and removal-related events and clinically significant consequences thereof among Nexplanon users in the US during standard clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Berlin Center for Epidemiology & Health Research, ZEG Berlin

Germany

First published: 06/08/2019

Last updated: 20/06/2024

Institution | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

Klaas Heinemann k.heinemann@zeg-berlin.de

Study contact

k.heinemann@zeg-berlin.de

Primary lead investigator

Klaas Heinemann

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2011

Actual: 04/04/2011

Study start date

Planned: 01/12/2011

Actual: 06/12/2011

Data analysis start date

Actual: 31/10/2017

Date of final study report

Planned: 01/02/2018

Actual: 20/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp and Dohme Corp

Study protocol

NORA Protocol_final.pdf(160.84 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to characterize the frequency of specific insertion-, localization- and removal-related events and clinically significant consequences thereof among Nexplanon users in the US during standard clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ETONOGESTREL

BARIUM SULFATE

Medical condition to be studied

Contraception

Population studied

Short description of the study population

Women with a newly-inserted Nexplanon contraceptive implant.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

7100

Study design details

Outcomes

- Characterize the insertion-, localization- and removal-related events, including incorrect insertion, localization of non-palpable implants and difficult removals- Describe the clinically significant consequences of these events, including pregnancy due to unrecognized non-insertion, injury to neurovascular structures in the arm and hospitalisation/surgery for localization/removal events, to monitor the occurrence of pregnancy and pregnancy outcomesto describe the reasons for (premature) discontinuation of Nexplanonto describe the baseline characteristics of Nexplanon users

Data analysis plan

Characterization of the frequency of specific insertion-, localization- and removal-related events among Nexplanon users under standard clinical practice will mostly be undertaken via point-estimates of the event rates as well as 95% confidence intervals. The impact of potential prognostic factors will be analyzed using multivariate regression models and/or stratified analyses. A complete data analysis plan, included mock tables will be developed within the next six months.

Documents

Study results

NORA_Final Report.pdf(8.72 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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Conflict of Interest Declaration for ENCEPP pdf.pdf(5.32 KB)

Composition of steering group and observers

NORA_SMAC Members_Updated.pdf(177.94 KB)

SMAC Membership for ENCEPP pdf.pdf(4.01 KB)

Signed code of conduct

2011-0006-CoC Declaration, 8 Nov 2011.pdf(29.51 KB)

Signed code of conduct checklist

2011-0006-CoC Checklist 8 Nov 2011.pdf(172.16 KB)

Signed checklist for study protocols

2011-0006-Study protocol Checklist, 8 Nov 2011.pdf(167.82 KB)

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