A Multicenter Trial to Evaluate the Insertion Characteristics of the Radiopaque Etonogestrel Implant Using a Next Generation Applicator (34530)(P05702)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00620035

First received: February 11, 2008
Last updated: August 26, 2015
Last verified: August 2015
History of Changes

Purpose

The primary purpose of this study is to evaluate the use of the next generation applicator and its instructions for proper insertion of the Radiopaque Implant. Secondary objectives include: evaluation of implant removal, evaluation of the overall contraceptive efficacy and safety of the Radiopaque Implant, assessment of x -ray visibility of the Radiopaque Implant, and to assess participant expectations and satisfaction with the Radiopaque Implant.

Condition	Intervention	Phase
Contraception	Drug: Radiopaque Etonogestrel Implant	Phase 3

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: An Open-Label, Non-Controlled Multicenter Trial to Evaluate the Insertion Characteristics of the Radiopaque Etonogestrel Implant Using a Next Generation Applicator

Resource links provided by NLM:

Drug Information available for: Etonogestrel

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Design & Technical

Aspects [Time Frame: Day 1] [Designated as safety issue: No]

In order to evaluate efficacy and ease of use of the Next Generation Applicator (NGA), the investigator/applicator user (AU) completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Design/technical aspects' consisted of five questions: fit of the applicator in the hand, size, weight, handling, and color of the applicator were assessed. The percentage of AUs who were very satisfied and satisfied was presented.

- Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Functionality [Time Frame: Day 1] [Designated as safety issue: No]

  In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Functionality' consisted of six questions assessing functionality of the needle. The percentage of AUs who were very satisfied and satisfied was presented.

- Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire by Domain: Safety [Time Frame: Day 1] [Designated as safety issue: No]

  In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Safety' consisted of three questions: removal of the protection cap from applicator, full retraction of the needle into the applicator after insertion, difference in colors of the obturator & the implant. The percentage of AUs who were very satisfied and satisfied was presented.

- Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Used Time [Time Frame: Day 1] [Designated as safety issue: No]

  In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Used Time' consisted of one question: insertion time was assessed. The percentage of AUs who were very satisfied and satisfied was presented.

- Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Applicator Satisfaction [Time Frame: Day 1] [Designated as safety issue: No]

  In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Applicator Satisfaction' consisted of one question in order to assess the applicator. The percentage of AUs who were very satisfied and satisfied was presented.

- Implant Insertion Time (Seconds) [Time Frame: Day 1] [Designated as safety issue: No]

  The implant insertion time was the time expressed in seconds, from removal of the protection cap from the applicator until retraction of the needle from the arm after insertion. Data was presented for overall investigators including experienced and non-experienced.

- Implant Removal Time (Seconds) [Time Frame: Day 1] [Designated as safety issue: No]

  The implant removal time was the time expressed in seconds, from making the removal incision until placing the butterfly closure. Data was presented for overall investigators including experienced and non-experienced.

Enrollment:	301
Study Start Date:	March 2007
Study Completion Date:	October 2010
Primary Completion Date:	October 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Radiopaque Etonogestrel Implant Radiopaque Etonogestrel Implant (drug) inserted with the Next Generation Applicator (NGA) The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.	Drug: Radiopaque Etonogestrel Implant One implant inserted for a 3-year treatment period Other Name: SCH 900415

Eligibility

Ages Eligible for Study: 18 Years to 40 Years
Genders Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Woman of at least (>=) 18 but not older than (<=)40 years of age at the time of screening;
- Good physical and mental health;
- Regular cycles with a usual length between 24 and 35 days;
- Body mass index >= 18 and <= 35 kg/m^2;
- Willing to give informed consent in writing.

Exclusion Criteria:

- Contraindications:
  - known or suspected pregnancy;
  - active venous thromboembolic disorder (e.g. deep vein thrombosis,

pulmonary embolism);

- presence or history of severe hepatic disease as long as liver function values have not returned to normal;
- malignancy or pre-malignancy, if sex-steroid-influenced;
- undiagnosed vaginal bleeding;
- hypersensitivity to any of the components of Radiopaque Implant.
  - Hypertension, i.e. systolic blood pressure >140 mmHg and/or diastolic blood pressure > 90 mmHg;
  - A history during pregnancy or during previous use of sex steroids of: jaundice and/or severe pruritus related to cholestasis, gallstone formation, porphyria, systemic lupus erythematosus, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis, otosclerosis-related hearing loss;
  - Present use or use during 2 months prior to the start of Radiopaque Implant of one of the following drugs: phenytoin, phenobarbital, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, ritonavir, nelfinavir, griseofulvin or the herbal remedy St John's wort;
  - Administration of investigational drugs within 2 months prior to the start of Radiopaque Implant

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

No publications provided by Merck Sharp & Dohme Corp.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Mommers E, Blum GF, Gent TG, Peters KP, Sørdal TS, Marintcheva-Petrova M. Nexplanon, a radiopaque etonogestrel implant in combination with a next-generation applicator: 3-year results of a noncomparative multicenter trial. Am J Obstet Gynecol. 2012 Nov;207(5):388.e1-6. doi: 10.1016/j.ajog.2012.08.002. Epub 2012 Aug 10.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00620035 History of Changes
Other Study ID Numbers: P05702 34530
Study First Received: February 11, 2008

Results First Received:	September 22, 2011
Last Updated:	August 26, 2015
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Norway: Norwegian Medicines Agency Sweden: Medical Products Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

3-keto-desogestrel
Desogestrel
Contraceptive Agents
Contraceptive Agents, Female
Contraceptives, Oral
Contraceptives, Oral, Synthetic
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Pharmacologic Actions
Physiological Effects of Drugs
Progestins
Reproductive Control Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: September 22, 2011

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Prevention
Condition:	Contraception
Intervention:	Drug: Radiopaque Etonogestrel Implant

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
At screening, a participant number was allocated to 308 participants of which 7 participants did not receive treatment. A total of 301 participants had an implant inserted.

Reporting Groups

	Description

Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Participant Flow: Overall Study

	Radiopaque Etonogestrel Implant
STARTED	**301**
COMPLETED	**156**
NOT COMPLETED	**145**
Adverse Event	**106**
Withdrawal of Informed Consent	**1**
Other Reason	**38**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Baseline Measures

	Radiopaque Etonogestrel Implant
Number of Participants [units: participants]	**301**
Age, Customized [units: participants]	
18-20 years	**43**

21-25 years	**79**
26-30 years	**64**
31-35 years	**54**
36-40 years	**61**
Gender [units: participants]	
Female	**301**
Male	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Design & Technical Aspects [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Design & Technical Aspects
Measure Description	In order to evaluate efficacy and ease of use of the Next Generation Applicator (NGA), the investigator/applicator user (AU) completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Design/technical aspects' consisted of five questions: fit of the applicator in the hand, size, weight, handling, and color of the applicator were assessed. The percentage of AUs who were very satisfied and satisfied was presented.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Applicator User (AU) group consisted of all investigators participating in the trial and who performed at least one insertion.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed [units: participants]	**23**

Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Design & Technical Aspects [units: Percentage of Applicator Users]	**99.1**

No statistical analysis provided for Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Design & Technical Aspects

2. Primary: Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Functionality [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Functionality
Measure Description	In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Functionality' consisted of six questions assessing functionality of the needle. The percentage of AUs who were very satisfied and satisfied was presented.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Applicator User (AU) group consisted of all investigators participating in the trial and who performed at least one insertion.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed [units: participants]	**23**
Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Functionality [units: Percentage of Applicator Users]	**94.9**

No statistical analysis provided for Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Functionality

3. Primary: Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire by Domain: Safety [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire by Domain: Safety
Measure Description	In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Safety' consisted of three questions: removal of the protection cap from applicator, full retraction of the needle into the applicator after insertion, difference in colors of the obturator & the implant. The percentage of AUs who were very satisfied and satisfied was presented.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Applicator User (AU) group consisted of all investigators participating in the trial and who performed at least one insertion.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed [units: participants]	**23**
Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire by Domain: Safety [units: Percentage of Applicator Users]	**98.6**

No statistical analysis provided for Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire by Domain: Safety

4. Primary: Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Used Time [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Used Time
Measure Description	In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction

	Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Used Time' consisted of one question: insertion time was assessed. The percentage of AUs who were very satisfied and satisfied was presented.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Applicator User (AU) group consisted of all investigators participating in the trial and who performed at least one insertion.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed [units: participants]	**23**
Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Used Time [units: Percentage of Applicator Users]	**100**

No statistical analysis provided for Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Used Time

5. Primary: Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Applicator Satisfaction [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Applicator Satisfaction
Measure Description	In order to evaluate efficacy and ease of use of the NGA, the investigator/AU completed a User Satisfaction Questionnaire on Day 1 after the 12th implant insertion. The domain, 'Applicator Satisfaction' consisted of one question in order to assess the applicator. The percentage of AUs who were very satisfied and satisfied was presented.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The Applicator User (AU) group consisted of all investigators participating in the trial and who performed at least one insertion.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed [units: participants]	**23**
Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Applicator Satisfaction [units: Percentage of Applicator Users]	**100**

No statistical analysis provided for Percentage of Applicator Users Who Were Very Satisfied and Satisfied- User Satisfaction Questionnaire for Domain: Applicator Satisfaction

6. Primary: Implant Insertion Time (Seconds) [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Implant Insertion Time (Seconds)
Measure Description	The implant insertion time was the time expressed in seconds, from removal of the protection cap from the applicator until retraction of the needle from the arm after insertion. Data was presented for overall investigators including experienced and non-experienced.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

All-Subjects-Treated (AST) group included all participants who had the Radiopaque implant inserted (N=301). Data was reported for 291 implant insertions.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray.

	The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed **[units: participants]**	**291**
Implant Insertion Time (Seconds) **[units: Seconds]** **Mean (Standard Deviation)**	**27.9 (29.3)**

No statistical analysis provided for Implant Insertion Time (Seconds)

7. Primary: Implant Removal Time (Seconds) [Time Frame: Day 1]

Measure Type	Primary
Measure Title	Implant Removal Time (Seconds)
Measure Description	The implant removal time was the time expressed in seconds, from making the removal incision until placing the butterfly closure. Data was presented for overall investigators including experienced and non-experienced.
Time Frame	Day 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All-Subjects-Treated (AST) group included all participants who had the Radiopaque implant inserted (N=301). Data was reported for 292 implant removals.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Measured Values

	Radiopaque Etonogestrel Implant
Number of Participants Analyzed	**292**

[units: participants]	
Implant Removal Time (Seconds) **[units: Seconds]** **Mean (Standard Deviation)**	**119.3 (120.2)**

No statistical analysis provided for Implant Removal Time (Seconds)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Safety data from the actual in-treatment period was used. The in-treatment period started on the day of the implant insertion and continued up to and including the fifth day after implant removal (3 years).
Additional Description	The safety analysis was performed for the AST group; all subjects who had the Radiopaque Implant inserted.

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Serious Adverse Events

	Radiopaque Etonogestrel Implant
Total, serious adverse events	
# participants affected / at risk	**17/301 (5.65%)**
Gastrointestinal disorders	
Abdominal Pain [1]	
# participants affected / at risk	**1/301 (0.33%)**
# events	**1**
Hepatobiliary disorders	
Jaundice [1]	
# participants affected / at risk	**1/301 (0.33%)**
# events	**1**
Infections and infestations	
Appendicitis [1]	
# participants affected / at risk	**2/301 (0.66%)**
# events	**2**
Campylobacter gastroenteritis [1]	
# participants affected / at risk	**1/301 (0.33%)**

# events	1
Salpingo-oophoritis [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Metabolism and nutrition disorders	
Hypoglycaemia [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Musculoskeletal and connective tissue disorders	
Intervertebral disc protrusion [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Breast Cancer [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Leiomyoma [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Thyroid Cancer [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Nervous system disorders	
Lethargy [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Migraine [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Sciatica [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Psychiatric disorders	
Bipolar Disorder [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Depression [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Suicide Attempt [1]	
# participants affected / at risk	1/301 (0.33%)
# events	1
Renal and urinary disorders	

Calculus Urinary [1]	
# participants affected / at risk	**1/301 (0.33%)**
# events	**1**
Reproductive system and breast disorders	
Ovarian Cyst [1]	
# participants affected / at risk	**1/301 (0.33%)**
# events	**1**

1 Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Safety data from the actual in-treatment period was used. The in-treatment period started on the day of the implant insertion and continued up to and including the fifth day after implant removal (3 years).
Additional Description	The safety analysis was performed for the AST group; all subjects who had the Radiopaque Implant inserted.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Radiopaque Etonogestrel Implant	The Radiopaque Implant is a single rod contraceptive implant of 4 cm length and 2 mm in diameter which is placed at the inner side of the non-dominant upper-arm about 8-10 cm above the medial epicondyle. The Radiopaque Implant contains approximately 68 mg etonogestrel (ENG) dispersed in a matrix of ethylene vinyl acetate (EVA) copolymer and barium sulfate, surrounded by an EVA membrane. The barium-sulfate provides radio-opacity and allows detection by X-ray. The ENG dose released from the implant amounts to about 60-70 mcg/day shortly after insertion and decreases to about 40 mcg/day at the start of the second year, and to about 25-30 mcg/day at the end of the third year.

Other Adverse Events

	Radiopaque Etonogestrel Implant
Total, other (not including serious) adverse events	
# participants affected / at risk	**233/301 (77.41%)**
General disorders	
Implant Site Haematoma [1]	
# participants affected / at risk	**16/301 (5.32%)**
# events	**16**
Implant Site Pain [1]	
# participants affected / at risk	**18/301 (5.98%)**
# events	**20**
Infections and infestations	
1	

Influenza	
# participants affected / at risk	**19/301 (6.31%)**
# events	**22**
Nasopharyngitis [1]	
# participants affected / at risk	**32/301 (10.63%)**
# events	**45**
Upper Respiratory Tract Infection [1]	
# participants affected / at risk	**20/301 (6.64%)**
# events	**30**
Urinary Tract Infection [1]	
# participants affected / at risk	**20/301 (6.64%)**
# events	**31**
Vulvovaginal Candidiasis [1]	
# participants affected / at risk	**19/301 (6.31%)**
# events	**26**
Investigations	
Weight Increased [1]	
# participants affected / at risk	**35/301 (11.63%)**
# events	**38**
Nervous system disorders	
Headache [1]	
# participants affected / at risk	**56/301 (18.60%)**
# events	**103**
Reproductive system and breast disorders	
Amenorrhoea [1]	
# participants affected / at risk	**21/301 (6.98%)**
# events	**23**
Dysmenorrhoea [1]	
# participants affected / at risk	**16/301 (5.32%)**
# events	**18**
Menorrhagia [1]	
# participants affected / at risk	**31/301 (10.30%)**
# events	**35**
Metrorrhagia [1]	
# participants affected / at risk	**53/301 (17.61%)**
# events	**60**
Vaginal Haemorrhage [1]	
# participants affected / at risk	**85/301 (28.24%)**
# events	**126**
Acne [1]	
# participants affected / at risk	**39/301 (12.96%)**
# events	**48**

1 Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** SPONSOR recognizes the right of the investigator(s) to publish, but all publications must be based on data validated and released by SPONSOR. Any such scientific paper, presentation, or other communication concerning the clinical trial described in protocol will first be submitted to SPONSOR, at least six weeks ahead of estimated publication or presentation, for written consent, which shall not be withheld unreasonably.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Mommers E, Blum GF, Gent TG, Peters KP, Sørdal TS, Marintcheva-Petrova M. Nexplanon, a radiopaque etonogestrel implant in combination with a next-generation applicator: 3-year results of a noncomparative multicenter trial. Am J Obstet Gynecol. 2012 Nov;207(5):388.e1-6. doi: 10.1016/j.ajog.2012.08.002. Epub 2012 Aug 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00620035 History of Changes
Other Study ID Numbers:	P05702 34530
Study First Received:	February 11, 2008
Results First Received:	September 22, 2011
Last Updated:	August 26, 2015
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Norway: Norwegian Medicines Agency

Sweden: Medical Products Agency
United Kingdom: Medicines and Healthcare Products Regulatory Agency

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