Effects on Ovarian Function of the Combined Oral Contraceptive NOMAC-E2 Compared to a COC Containing DRSP/EE (292003)(COMPLETED)(P05723)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00511433

First received: August 2, 2007
Last updated: November 14, 2014
Last verified: November 2014
History of Changes

Purpose

The primary purpose of this study is to evaluate the effects of the nomegestrol acetate-estradiol (NOMAC-E2) combined oral contraceptive (COC) on ovarian function.

Condition	Intervention	Phase
Contraception	Drug: NOMAC-E2 Drug: DRSP-EE	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Pharmacodynamics Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: A Randomized, Open-Label, Comparative Trial to Evaluate the Effects on Ovarian Function of a Monophasic Combined Oral Contraceptive (COC) Containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2), Compared to a Monophasic COC Containing 3 mg Drospirenone (DRSP) and 30 ug Ethinyl Estradiol (EE)

Resource links provided by NLM:

Drug Information available for: Estradiol Ethinylestradiol Estradiol cypionate Estradiol valerate Estradiol acetate Estradiol hemihydrate Drospirenone

U.S. FDA Resources

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

Primary Outcome Measures:

- Effect on Ovarian Function as Determined by the Number of Participants With an Occurrence of Ovulation [Time Frame: Cycle 1, Cycle 2, and Cycle 6] [Designated as safety issue: No]

  During treatment, ovulation was assessed for each participant by the investigator on the basis of ultrasound scanning (USS). The final analysis was based on assessor-blind adjudication.

- Effect on Ovarian Function as Determined by the Maximum Follicle Diameter [Time Frame: Screening cycle, Cycle 1, Cycle 2, Cycle 3, and Cycle 6] [Designated as safety issue: No]

  The maximum follicular diameter was defined as the largest follicular diameter during a treatment cycle.

- Effect on Ovarian Function as Determined by the Maximum Progesterone Value [Time Frame: Screening cycle, Cycle 1, Cycle 2, Cycle 3, and Cycle 6] [Designated as safety issue: No]

  The maximum progesterone value was defined as the largest value during a cycle.

- Effect on Ovarian Function as Determined by 17 Beta-estradiol (E2) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6] [Designated as safety issue: No]

  The parameter was measured at pre-defined study days.

- Effect on Ovarian Function as Determined by Follicle Stimulating Hormone (FSH) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6] [Designated as safety issue: No]

  The parameter was measured at pre-defined study days.

- Effect on Ovarian Function as Determined by Luteinizing Hormone (LH) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6] [Designated as safety issue: No]

  The parameter was measured at pre-defined study days.

Secondary Outcome Measures:

- Effect on Cervical Mucus as Determined by Insler Score [Time Frame: Screening Cycle, Cycle 1, Cycle 2, and Cycle 7 (post-treatment cycle)] [Designated as safety issue: No]

  The Insler Score was assessed on Day 6 after ovulation during the Screening Cycle, on Day 21 of Cycle 1, and when the maximum follicle diameter was greater than or equal to 15 mm. The Insler Score consisted of four categories each scaled from 0 (none) to 3 (complete). The higher the score, the greater the cervical reaction.

- Effect on Maximum Endometrial Thickness [Time Frame: Screening Cycle, Cycle 1, Cycle 2, and Cycle 6] [Designated as safety issue: No]

  Maximum endometrial thickness was defined as the largest endometrial thickness during a cycle.

- Number of In-treatment Pregnancies (With +2 Day Window) Per 100 Woman Years of Exposure (Pearl Index) [Time Frame: 6 cycles] [Designated as safety issue: No]

  In-treatment pregnancies were pregnancies with an estimated date of conception from the day of first intake of trial medication up to and including the day of last (active or placebo) intake of trial medication extended with a maximum of two days. Each 13 cycles (28 days per cycle) of exposure constitutes a woman year. The Pearl Index was obtained by dividing the number of in-treatment pregnancies that occurred by the time (in 100 woman years) that the women were under risk of becoming pregnant.

- Number of Participants With an Occurrence of Breakthrough Bleeding/Spotting [Time Frame: Every 28-day cycle for 6 cycles] [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding/spotting was defined as any episode that occurred during the "expected non-bleeding period" that was neither an early nor a continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.

- Number of Participants With an Occurrence of Absence of Withdrawal Bleeding [Time Frame: Every 28-day cycle for 6 cycles] [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Absence of withdrawal bleeding was defined as no bleeding/spotting episode that began during or continued into the "expected bleeding period". Expected

bleeding period: DRSP-EE group: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.

- Number of Participants With an Occurrence of Breakthrough Bleeding [Time Frame: Every 28-day cycle for 6 cycles]
  [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding was defined as any bleeding episode that occurred during the "expected non-bleeding period" that was neither part of an early nor continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2:21-day period starting on Day 4 of the cycle.

- Number of Participants With an Occurrence of Breakthrough Spotting (Spotting Only) [Time Frame: Every 28-day cycle for 6 cycles]
  [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough spotting was defined as any spotting episode that occurred during the "expected non-bleeding period" that was neither part of an early nor continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2:21-day period starting on Day 4 of the cycle.

- Number of Participants With an Occurrence of Early Withdrawal Bleeding [Time Frame: Every 28-day cycle for 6 cycles]
  [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Early withdrawal bleeding was defined as any withdrawal bleeding that started before the current "expected bleeding period". Expected bleeding period: DRSP-EE: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.

- Number of Participants With an Occurrence of Continued Withdrawal Bleeding [Time Frame: Every 28-day cycle for 5 cycles]
  [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Continued withdrawal bleeding was defined as any withdrawal bleeding that continued into the "expected non-bleeding period" of the next cycle. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.

- Average Number of Breakthrough Bleeding/Spotting Days [Time Frame: Every 28-day cycle for 6 cycles] [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding/spotting was defined as any episode that occurred during the "expected non-bleeding period" that was neither an early nor a continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.

- Average Number of Withdrawal Bleeding Days [Time Frame: Every 28-day cycle for 6 cycles] [Designated as safety issue: No]

  Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Withdrawal bleeding was defined as bleeding/spotting episode that started during or continued into the "expected bleeding period". Expected bleeding period: DRSP-EE group: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.

Enrollment:	48
Study Start Date:	October 2006
Study Completion Date:	January 2008
Primary Completion Date:	January 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: NOMAC-E2 Nomegestrol Acetate (NOMAC) and Estradiol (E2), 2.5	Drug: NOMAC-E2 Nomegestrol Acetate and Estradiol Tablets, 2.5 mg NOMAC and 1.5 mg E2 taken

mg NOMAC and 1.5 mg E2 monophasic combined oral contraceptive	once daily from Day 1 of menstrual period up to and including Day 28 for 6 consecutive 28-day menstrual cycles.
Active Comparator: DRSP-EE Drospirenone (DRSP) and Ethinyl Estradiol (EE), 3 mg DRSP and 30 mcg EE monophasic combined oral contraceptive	Drug: DRSP-EE Drospirenone and Ethinyl Estradiol Tablets, 3 mg DRSP and 30 mcg EE taken once daily from Day 1 of menstrual period up to and including Day 28 for 6 consecutive 28-day menstrual cycles.

Eligibility

Ages Eligible for Study: 18 Years to 35 Years
Genders Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Willing to use COC for at least 6 cycles.
- 18 - 35 years of age at screening.
- Body Mass Index (BMI) of >/= 17 and </= 35.
- Good physical and mental health.
- Willing to use condoms as the sole contraceptive method during screening cycle and 1 post-treatment cycle.
- Willing to give informed consent.

Exclusion Criteria:

- Contraindications for contraceptive steroids (general).
- Additional contraindications (renal, hepatic or adrenal insufficiency).
- Breastfeeding.
- Present use (or use within 2 months prior to start of the trial medication) of the following drugs: phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate, rifampicin, nelfinavir, ritonavir, griseofulvin, ketoconazole, sex

steroids (other than pre- and post treatment contraceptive method) and herbal remedies containing Hypericum perforatum (St. John's Wort).

- Administration of any other investigational drugs and/or participation in another clinical trial within 2 months prior to the start of the trial medication or during the trial period.
- Abnormal cervical smear at screening, or documentation of an abnormal smear performed within 6 months before screening.
- Clinically relevant abnormal laboratory result at screening as judged by the investigator.

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

Publications:

Duijkers IJ, Klipping C, Grob P, Korver T. Effects of a monophasic combined oral contraceptive containing nomegestrol acetate and 17 beta-oestradiol on ovarian function in comparison to a monophasic combined oral contraceptive containing drospirenone and ethinylestradiol. Eur J Contracept Reprod Health Care. 2010 Oct;15(5):314-25. doi: 10.3109/13625187.2010.504313.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00511433 History of Changes
Other Study ID Numbers: P05723 Organon protocol 292003
Study First Received: August 2, 2007

Results First Received:	July 28, 2011
Last Updated:	November 14, 2014
Health Authority:	Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Additional relevant MeSH terms:

Contraceptive Agents	Diuretics
Contraceptives, Oral	Diuretics, Potassium Sparing
Contraceptives, Oral, Combined	Estrogens
Drospirenone	Hormone Antagonists
Estradiol	Hormones
Estradiol 17 beta-cypionate	Hormones, Hormone Substitutes, and Hormone Antagonists
Estradiol 3-benzoate	Mineralocorticoid Receptor Antagonists
Estradiol valerate	Natriuretic Agents
Ethinyl Estradiol	Pharmacologic Actions
Polyestradiol phosphate	Physiological Effects of Drugs
Cardiovascular Agents	Reproductive Control Agents
Contraceptive Agents, Female	Therapeutic Uses

ClinicalTrials.gov processed this record on May 08, 2016

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First received: August 2, 2007
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History of Changes

Results First Received: July 28, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Pharmacodynamics Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Condition:	Contraception
Interventions:	Drug: NOMAC-E2 Drug: DRSP-EE

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
No text entered.

Reporting Groups

	Description

NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Participant Flow: Overall Study

	NOMAC-E2	DRSP-EE
STARTED	32	16
COMPLETED	26	15
NOT COMPLETED	6	1
Adverse Event	5	0
Other Reason	1	1

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
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
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Total	Total of all reporting groups

Baseline Measures

	NOMAC-E2	DRSP-EE	Total
Number of Participants [units: participants]	32	16	48
Age [units: years] Mean (Standard Deviation)	22.8 (3.3)	22.9 (4.3)	22.8 (3.6)
Gender [units: participants]			
Female	32	16	48

Male	**0**	**0**	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Effect on Ovarian Function as Determined by the Number of Participants With an Occurrence of Ovulation [Time Frame: Cycle 1, Cycle 2, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by the Number of Participants With an Occurrence of Ovulation
Measure Description	During treatment, ovulation was assessed for each participant by the investigator on the basis of ultrasound scanning (USS). The final analysis was based on assessor-blind adjudication.
Time Frame	Cycle 1, Cycle 2, and Cycle 6
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.
Intent-to-treat (ITT) group consisted of all participants who were treated. n=number of participants completing the respective cycle with non-missing values.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by the Number of Participants With an Occurrence of Ovulation [units: Participants]		
Cycle 1 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**0**	**0**
Cycle 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**0**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**0**	**0**

No statistical analysis provided for Effect on Ovarian Function as Determined by the Number of Participants With an Occurrence of Ovulation

2. Primary: Effect on Ovarian Function as Determined by the Maximum Follicle Diameter [Time Frame: Screening cycle, Cycle 1, Cycle 2, Cycle

3, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by the Maximum Follicle Diameter
Measure Description	The maximum follicular diameter was defined as the largest follicular diameter during a treatment cycle.
Time Frame	Screening cycle, Cycle 1, Cycle 2, Cycle 3, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants completing the respective cycle with non-missing values.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by the Maximum Follicle Diameter [units: millimeters (mm)] Mean (Standard Deviation)		
Screening cycle (n=32 NOMAC-E2 / n=16 DRSP-EE)	**19.3 (3.13)**	**19.6 (4.32)**
Cycle 1 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**7.6 (1.51)**	**8.1 (1.98)**
Cycle 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**8.2 (1.82)**	**10.8 (4.76)**
Cycle 3 (n=27 NOMAC-E2 / n=14 DRSP-EE)	**7.8 (1.88)**	**8.4 (2.31)**
Cycle 6 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**6.9 (2.07)**	**7.4 (2.06)**

No statistical analysis provided for Effect on Ovarian Function as Determined by the Maximum Follicle Diameter

3. Primary: Effect on Ovarian Function as Determined by the Maximum Progesterone Value [Time Frame: Screening cycle, Cycle 1, Cycle 2, Cycle 3, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by the Maximum Progesterone Value
Measure Description	The maximum progesterone value was defined as the largest value during a cycle.
Time Frame	Screening cycle, Cycle 1, Cycle 2, Cycle 3, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants completing the respective cycle with non-missing values.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by the Maximum Progesterone Value [units: nanomoles per liter (nmol/L)] Mean (Standard Deviation)		
Screening cycle (n=32 NOMAC-E2 / n=16 DRSP-EE)	**38.7 (12.62)**	**38.7 (17.01)**
Cycle 1 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**1.7 (0.46)**	**1.6 (0.28)**
Cycle 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**1.5 (0.46)**	**1.5 (0.26)**
Cycle 3 (n=27 NOMAC-E2 / n=14 DRSP-EE)	**1.26 (0.10)**	**1.34 (0.27)**
Cycle 6 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**1.3 (0.29)**	**1.5 (0.26)**

No statistical analysis provided for Effect on Ovarian Function as Determined by the Maximum Progesterone Value

4. Primary: Effect on Ovarian Function as Determined by 17 Beta-estradiol (E2) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by 17 Beta-estradiol (E2)
Measure Description	The parameter was measured at pre-defined study days.

Time Frame	Cycle 1, Cycle 2, Cycle 3, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants with non-missing values at the respective time point.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by 17 Beta-estradiol (E2) **[units: picomoles per liter (pmol/L)]** **Mean (Standard Deviation)**		
Cycle 1, Day 2 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**168.75 (62.37)**	**79.82 (18.34)**
Cycle 1, Day 5 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**194.57 (93.17)**	**66.66 (10.53)**
Cycle 1, Day 8 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**172.35 (66.92)**	**61.15 (3.66)**
Cycle 1, Day 11 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**184.63 (95.70)**	**60.51 (1.96)**
Cycle 1, Day 14 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**197.57 (123.23)**	**60.26 (1.48)**
Cycle 1, Day 18 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**182.72 (84.03)**	**60.58 (2.93)**
Cycle 1, Day 21 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**191.08 (139.50)**	**59.82 (0)**
Cycle 1, Day 24 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**232.80 (281.15)**	**69.84 (23.50)**
Cycle 1, Day 27 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**99.65 (42.53)**	**150.79 (46.45)**
Cycle 2, Day 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**176.43 (91.99)**	**135.86 (106.62)**
Cycle 2, Day 5 (n=29 NOMAC-E2 / n=15 DRSP-EE)	**213.64 (104.85)**	**142.74 (186.99)**
Cycle 2, Day 8 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**192.59 (68.83)**	**131.98 (196.51)**
Cycle 2, Day 11 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**185.77 (63.97)**	**112.23 (152.19)**

Cycle 2, Day 14 (n=29 NOMAC-E2 / n=15 DRSP-EE)	**183.66 (74.39)**	**78.44 (69.99)**
Cycle 2, Day 18 (n=28 NOMAC-E2 / n=15 DRSP-EE)	**213.84 (123.35)**	**60.11 (0.95)**
Cycle 2, Day 21 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**192.47 (66.43)**	**59.91 (0.37)**
Cycle 2, Day 24 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**206.20 (147.27)**	**61.33 (3.95)**
Cycle 2, Day 27 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**97.99 (40.88)**	**155.63 (63.65)**
Cycle 3, Day 2 (n=27 NOMAC-E2 / n=14 DRSP-EE)	**148.16 (52.09)**	**141.11 (115.89)**
Cycle 6, Day 14 (n=25 NOMAC-E2 / n=14 DRSP-EE)	**205.89 (104.45)**	**59.98 (0.59)**
Cycle 6, Day 18 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**200.04 (90.28)**	**64.20 (12.99)**
Cycle 6, Day 21 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**188.47 (90.12)**	**60.82 (3.02)**
Cycle 6, Day 24 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**187.16 (106.60)**	**69.60 (33.97)**
Cycle 6, Day 27 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**99.51 (35.60)**	**133.49 (61.28)**

No statistical analysis provided for Effect on Ovarian Function as Determined by 17 Beta-estradiol (E2)

5. Primary: Effect on Ovarian Function as Determined by Follicle Stimulating Hormone (FSH) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by Follicle Stimulating Hormone (FSH)
Measure Description	The parameter was measured at pre-defined study days.
Time Frame	Cycle 1, Cycle 2, Cycle 3, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants with non-missing values at the respective time point.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	

		DRSP-EE
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by Follicle Stimulating Hormone (FSH) **[units: International units per liter (IU/L)]** **Mean (Standard Deviation)**		
Cycle 1, Day 2 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**4.29 (1.45)**	**4.51 (1.14)**
Cycle 1, Day 5 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**4.08 (1.59)**	**4.23 (1.33)**
Cycle 1, Day 8 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**3.59 (1.59)**	**3.40 (1.57)**
Cycle 1, Day 11 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**3.44 (2.07)**	**2.46 (1.40)**
Cycle 1, Day 14 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**3.06 (1.90)**	**2.32 (1.71)**
Cycle 1, Day 18 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**2.95 (1.76)**	**1.91 (1.69)**
Cycle 1, Day 21 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**2.87 (1.96)**	**1.61 (1.53)**
Cycle 1, Day 24 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**2.88 (1.99)**	**4.50 (4.05)**
Cycle 1, Day 27 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**5.42 (2.51)**	**7.91 (3.95)**
Cycle 2, Day 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**5.32 (2.05)**	**5.48 (1.82)**
Cycle 2, Day 5 (n=29 NOMAC-E2 / n=15 DRSP-EE)	**4.59 (1.54)**	**4.08 (1.54)**
Cycle 2, Day 8 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**3.99 (1.71)**	**2.77 (1.19)**
Cycle 2, Day 11 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**3.47 (1.68)**	**1.96 (1.13)**
Cycle 2, Day 14 (n=29 NOMAC-E2 / n=15 DRSP-EE)	**3.34 (2.18)**	**1.44 (1.00)**
Cycle 2, Day 18 (n=28 NOMAC-E2 / n=15 DRSP-EE)	**3.18 (1.84)**	**1.22 (0.94)**
Cycle 2, Day 21 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**3.02 (1.64)**	**1.04 (0.98)**
Cycle 2, Day 24 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**3.05 (1.76)**	**3.52 (3.51)**
Cycle 2, Day 27 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**5.92 (2.77)**	**6.99 (2.78)**
Cycle 3, Day 2 (n=27 NOMAC-E2 / n=14 DRSP-EE)	**6.01 (2.08)**	**5.17 (1.44)**
Cycle 6, Day 14 (n=25 NOMAC-E2 / n=14 DRSP-EE)	**3.08 (1.88)**	**1.43 (1.32)**
	2.82 (1.79)	**1.29 (1.28)**

Cycle 6, Day 18 (n=26 NOMAC-E2 / n=15 DRSP-EE)		
Cycle 6, Day 21 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**3.30 (2.14)**	**0.92 (0.96)**
Cycle 6, Day 24 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**2.86 (2.09)**	**3.18 (3.04)**
Cycle 6, Day 27 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**5.65 (2.57)**	**6.22 (2.99)**

No statistical analysis provided for Effect on Ovarian Function as Determined by Follicle Stimulating Hormone (FSH)

6. Primary: Effect on Ovarian Function as Determined by Luteinizing Hormone (LH) [Time Frame: Cycle 1, Cycle 2, Cycle 3, and Cycle 6]

Measure Type	Primary
Measure Title	Effect on Ovarian Function as Determined by Luteinizing Hormone (LH)
Measure Description	The parameter was measured at pre-defined study days.
Time Frame	Cycle 1, Cycle 2, Cycle 3, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants with non-missing values at the respective time point.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Ovarian Function as Determined by Luteinizing Hormone (LH) **[units: IU/L]** **Mean (Standard Deviation)**		
Cycle 1, Day 2 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**3.73 (1.64)**	**3.69 (1.58)**
Cycle 1, Day 5 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**2.98 (1.49)**	**4.34 (2.35)**

Cycle 1, Day 8 (n=32 NOMAC-E2 / n=16 DRSP-EE)	2.50 (1.68)	3.09 (2.36)
Cycle 1, Day 11 (n=30 NOMAC-E2 / n=16 DRSP-EE)	2.13 (1.50)	1.89 (1.45)
Cycle 1, Day 14 (n=29 NOMAC-E2 / n=16 DRSP-EE)	1.85 (1.77)	2.32 (2.05)
Cycle 1, Day 18 (n=29 NOMAC-E2 / n=16 DRSP-EE)	1.76 (1.41)	1.61 (1.29)
Cycle 1, Day 21 (n=30 NOMAC-E2 / n=16 DRSP-EE)	1.45 (1.33)	1.19 (0.86)
Cycle 1, Day 24 (n=30 NOMAC-E2 / n=16 DRSP-EE)	1.59 (1.44)	2.63 (2.07)
Cycle 1, Day 27 (n=30 NOMAC-E2 / n=16 DRSP-EE)	3.04 (1.95)	4.34 (2.38)
Cycle 2, Day 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	3.47 (2.20)	4.81 (3.01)
Cycle 2, Day 5 (n=29 NOMAC-E2 / n=15 DRSP-EE)	3.04 (1.94)	5.08 (3.21)
Cycle 2, Day 8 (n=29 NOMAC-E2 / n=16 DRSP-EE)	2.48 (1.85)	3.33 (1.97)
Cycle 2, Day 11 (n=29 NOMAC-E2 / n=16 DRSP-EE)	2.54 (2.01)	2.70 (2.18)
Cycle 2, Day 14 (n=29 NOMAC-E2 / n=15 DRSP-EE)	2.39 (2.17)	1.69 (1.42)
Cycle 2, Day 18 (n=28 NOMAC-E2 / n=15 DRSP-EE)	2.05 (1.76)	1.60 (1.31)
Cycle 2, Day 21 (n=27 NOMAC-E2 / n=16 DRSP-EE)	1.68 (1.44)	0.97 (0.67)
Cycle 2, Day 24 (n=27 NOMAC-E2 / n=16 DRSP-EE)	1.81 (1.75)	2.38 (2.01)
Cycle 2, Day 27 (n=27 NOMAC-E2 / n=16 DRSP-EE)	3.37 (2.90)	3.92 (2.17)
Cycle 3, Day 2 (n=27 NOMAC-E2 / n=14 DRSP-EE)	3.71 (2.23)	4.79 (2.67)
Cycle 6, Day 14 (n=25 NOMAC-E2 / n=14 DRSP-EE)	2.29 (1.86)	2.15 (2.83)
Cycle 6, Day 18 (n=26 NOMAC-E2 / n=15 DRSP-EE)	1.88 (2.05)	1.27 (1.02)
Cycle 6, Day 21 (n=26 NOMAC-E2 / n=15 DRSP-EE)	2.00 (1.68)	1.14 (0.89)
Cycle 6, Day 24 (n=26 NOMAC-E2 / n=14 DRSP-EE)	1.85 (1.75)	2.56 (2.12)
Cycle 6, Day 27 (n=26 NOMAC-E2 / n=15 DRSP-EE)	3.13 (2.21)	4.03 (2.57)

No statistical analysis provided for Effect on Ovarian Function as Determined by Luteinizing Hormone (LH)

7. Secondary: Effect on Cervical Mucus as Determined by Insler Score [Time Frame: Screening Cycle, Cycle 1, Cycle 2, and Cycle 7 (post-treatment cycle)]

Measure Type	Secondary
Measure Title	Effect on Cervical Mucus as Determined by Insler Score
Measure Description	The Insler Score was assessed on Day 6 after ovulation during the Screening Cycle, on Day 21 of Cycle 1, and when the maximum follicle diameter was greater than or equal to 15 mm. The Insler Score consisted of four categories each scaled from 0 (none) to 3 (complete). The higher the score, the greater the cervical reaction.
Time Frame	Screening Cycle, Cycle 1, Cycle 2, and Cycle 7 (post-treatment cycle)
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.
ITT group consisted of all participants who were treated. n=number of participants with non-missing values at the respective time point.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Cervical Mucus as Determined by Insler Score **[units: score on a scale]** **Mean (Standard Deviation)**		
Screening cycle (n=32 NOMAC-E2 / n=16 DRSP-EE)	**8.9 (2.55)**	**7.3 (3.61)**
Cycle 1 (n=30 NOMAC-E2 / n=15 DRSP-EE)	**2.3 (1.93)**	**3.2 (2.43)**
Cycle 2 (n=0 NOMAC-E2 / n=2 DRSP-EE)	**NA** [1]	**4.5 (0.71)**
Cycle 7 (n=22 NOMAC-E2 / n=15 DRSP-EE)	**7.0 (2.94)**	**8.7 (1.53)**

[1] Mean and standard deviation do not apply for zero participants.

No statistical analysis provided for Effect on Cervical Mucus as Determined by Insler Score

8. Secondary: Effect on Maximum Endometrial Thickness [Time Frame: Screening Cycle, Cycle 1, Cycle 2, and Cycle 6]

Measure Type	Secondary
Measure Title	Effect on Maximum Endometrial Thickness
Measure Description	Maximum endometrial thickness was defined as the largest endometrial thickness during a cycle.
Time Frame	Screening Cycle, Cycle 1, Cycle 2, and Cycle 6
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.
ITT group consisted of all participants who were treated. n=number of participants completing the respective cycle.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**32**	**16**
Effect on Maximum Endometrial Thickness [units: mm] Mean (Standard Deviation)		
Screening cycle (n=32 NOMAC-E2 / n=16 DRSP-EE)	**9.9 (1.91)**	**10.1 (2.50)**
Cycle 1 (n=32 NOMAC-E2 / n=16 DRSP-EE)	**5.9 (1.22)**	**6.1 (1.25)**
Cycle 2 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**5.3 (0.71)**	**6.8 (1.73)**
Cycle 6 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**4.9 (0.66)**	**5.5 (1.30)**

No statistical analysis provided for Effect on Maximum Endometrial Thickness

9. Secondary: Number of In-treatment Pregnancies (With +2 Day Window) Per 100 Woman Years of Exposure (Pearl Index) [Time Frame: 6 cycles]

Measure Type	Secondary
Measure Title	Number of In-treatment Pregnancies (With +2 Day Window) Per 100 Woman Years of Exposure (Pearl Index)

Measure Description	In-treatment pregnancies were pregnancies with an estimated date of conception from the day of first intake of trial medication up to and including the day of last (active or placebo) intake of trial medication extended with a maximum of two days. Each 13 cycles (28 days per cycle) of exposure constitutes a woman year. The Pearl Index was obtained by dividing the number of in-treatment pregnancies that occurred by the time (in 100 woman years) that the women were under risk of becoming pregnant.
Time Frame	6 cycles
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 "restricted ITT" set included all participants treated and excluded nonpregnant participants who didn't have >=1 cycle expected to be at risk for pregnancy (with recorded use of condoms or without sexual intercourse per diary card data).

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**24**	**12**
Number of woman years (rounded to nearest integer) Analyzed [units: woman years (rounded to nearest integer)]	**8**	**5**
Number of In-treatment Pregnancies (With +2 Day Window) Per 100 Woman Years of Exposure (Pearl Index) [units: Pregnancies per 100 woman years] Number (95% Confidence Interval)	**0 (0 to 45.9)**	**0 (0 to 72.7)**

No statistical analysis provided for Number of In-treatment Pregnancies (With +2 Day Window) Per 100 Woman Years of Exposure (Pearl Index)

10. Secondary: Number of Participants With an Occurrence of Breakthrough Bleeding/Spotting [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Breakthrough Bleeding/Spotting
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding/spotting was defined as any episode that occurred during the "expected non-bleeding period" that was neither an early nor a continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.
Time Frame	Every 28-day cycle for 6 cycles
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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n=number of participants with evaluable cycles.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Breakthrough Bleeding/Spotting [units: Participants]		
Cycle 1 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**7**	**1**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**6**	**0**
Cycle 3 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**5**	**0**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**5**	**0**
Cycle 5 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**8**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**5**	**0**

No statistical analysis provided for Number of Participants With an Occurrence of Breakthrough Bleeding/Spotting

11. Secondary: Number of Participants With an Occurrence of Absence of Withdrawal Bleeding [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Absence of Withdrawal Bleeding
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Absence of withdrawal bleeding was defined as no bleeding/spotting episode that began during or continued into the "expected bleeding period". Expected bleeding period: DRSP-EE group: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.
Time Frame	Every 28-day cycle for 6 cycles

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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n=number of participants with evaluable cycles.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Absence of Withdrawal Bleeding [units: Participants]		
Cycle 1 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**3**	**0**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**2**	**0**
Cycle 3 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**2**	**0**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**2**	**0**
Cycle 5 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**2**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**4**	**1**

No statistical analysis provided for Number of Participants With an Occurrence of Absence of Withdrawal Bleeding

12. Secondary: Number of Participants With an Occurrence of Breakthrough Bleeding [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Breakthrough Bleeding
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding was defined as any bleeding episode that occurred during the "expected non-bleeding period" that was neither part of an early nor continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2:21-day period starting on Day 4 of the cycle.

Time Frame	Every 28-day cycle for 6 cycles
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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n=number of participants with evaluable cycles.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Breakthrough Bleeding [units: Participants]		
Cycle 1 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**0**	**0**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**0**	**0**
Cycle 3 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**0**	**0**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**1**	**0**
Cycle 5 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**1**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**0**	**0**

No statistical analysis provided for Number of Participants With an Occurrence of Breakthrough Bleeding

13. Secondary: Number of Participants With an Occurrence of Breakthrough Spotting (Spotting Only) [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Breakthrough Spotting (Spotting Only)
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough spotting was defined as any spotting episode that occurred during the "expected non-bleeding period" that was neither part of an early nor continued withdrawal bleeding. Expected non-

	bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2:21-day period starting on Day 4 of the cycle.
Time Frame	Every 28-day cycle for 6 cycles
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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n=number of participants with evaluable cycles.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Breakthrough Spotting (Spotting Only) [units: Participants]		
Cycle 1 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**7**	**1**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**6**	**0**
Cycle 3 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**5**	**0**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**4**	**0**
Cycle 5 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**7**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**5**	**0**

No statistical analysis provided for Number of Participants With an Occurrence of Breakthrough Spotting (Spotting Only)

14. Secondary: Number of Participants With an Occurrence of Early Withdrawal Bleeding [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Early Withdrawal Bleeding
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Early withdrawal bleeding was defined as any withdrawal bleeding that started

	before the current "expected bleeding period". Expected bleeding period: DRSP-EE: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.
Time Frame	Every 28-day cycle for 6 cycles
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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n= number of participants with evaluable cycles.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Early Withdrawal Bleeding [units: Participants]		
Cycle 1 (n=30 NOMAC-E2 / n=16 DRSP-EE)	**4**	**2**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**4**	**0**
Cycle 3 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**1**	**0**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**2**	**0**
Cycle 5 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**1**	**0**
Cycle 6 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**2**	**0**

No statistical analysis provided for Number of Participants With an Occurrence of Early Withdrawal Bleeding

15. Secondary: Number of Participants With an Occurrence of Continued Withdrawal Bleeding [Time Frame: Every 28-day cycle for 5 cycles]

Measure Type	Secondary
Measure Title	Number of Participants With an Occurrence of Continued Withdrawal Bleeding
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was

	considered to be spotting or bleeding. Continued withdrawal bleeding was defined as any withdrawal bleeding that continued into the "expected non-bleeding period" of the next cycle. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.
Time Frame	Every 28-day cycle for 5 cycles
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 ITT group consisted of all participants who were treated; ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles. n=number of participants with evaluable cycles (except for the very last cycle of a participant for which this parameter was not defined).
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles. n=number of participants with evaluable cycles (except for the very last cycle of a participant for which this parameter was not defined).

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Number of Participants With an Occurrence of Continued Withdrawal Bleeding [units: Participants]		
Cycle 1 (n=29 NOMAC-E2 / n=16 DRSP-EE)	**11**	**12**
Cycle 2 (n=27 NOMAC-E2 / n=16 DRSP-EE)	**8**	**10**
Cycle 3 (n=25 NOMAC-E2 / n=15 DRSP-EE)	**8**	**11**
Cycle 4 (n=26 NOMAC-E2 / n=15 DRSP-EE)	**12**	**12**
Cycle 5 (n=26 NOMAC-E2 / n=14 DRSP-EE)	**9**	**10**

No statistical analysis provided for Number of Participants With an Occurrence of Continued Withdrawal Bleeding

16. Secondary: Average Number of Breakthrough Bleeding/Spotting Days [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Average Number of Breakthrough Bleeding/Spotting Days

Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Breakthrough bleeding/spotting was defined as any episode that occurred during the "expected non-bleeding period" that was neither an early nor a continued withdrawal bleeding. Expected non-bleeding period: DRSP-EE group: 21-day period starting on Day 1 of the cycle; NOMAC-E2: 21-day period starting on Day 4 of the cycle.
Time Frame	Every 28-day cycle for 6 cycles
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.
ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n= number of participants who had breakthrough bleeding/spotting for the respective cycle.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Average Number of Breakthrough Bleeding/Spotting Days [units: Days] Mean (Standard Deviation)		
Cycle 1 (n=7 NOMAC-E2; n=1 DRSP-EE)	**3.0 (2.2)**	**2.0** [1]
Cycle 2 (n=6 NOMAC-E2; n=0 DRSP-EE)	**2.7 (1.9)**	**NA** [2]
Cycle 3 (n=5 NOMAC-E2; n=0 DRSP-EE)	**2.2 (1.1)**	**NA** [2]
Cycle 4 (n=5 NOMAC-E2; n=0 DRSP-EE)	**4.0 (2.8)**	**NA** [2]
Cycle 5 (n=8 NOMAC-E2; n=0 DRSP-EE)	**3.5 (2.3)**	**NA** [2]
Cycle 6 (n=5 NOMAC-E2; n=0 DRSP-EE)	**3.6 (2.1)**	**NA** [2]

[1] Value for one participant; therefore, standard deviation does not apply.
[2] Mean and standard deviation do not apply for zero participants.

No statistical analysis provided for Average Number of Breakthrough Bleeding/Spotting Days

17. Secondary: Average Number of Withdrawal Bleeding Days [Time Frame: Every 28-day cycle for 6 cycles]

Measure Type	Secondary
Measure Title	Average Number of Withdrawal Bleeding Days
Measure Description	Cycle control was evaluated on the basis of vaginal bleeding pattern as recorded daily by participants using diary card booklets. Participants documented whether vaginal bleeding was present, and if present, indicated whether it was considered to be spotting or bleeding. Withdrawal bleeding was defined as bleeding/spotting episode that started during or continued into the "expected bleeding period". Expected bleeding period: DRSP-EE group: 7-day period starting on Day 22 of the cycle; NOMAC-E2: 7-day period starting on Day 25 of the cycle and ending on Day 3 of the next cycle.
Time Frame	Every 28-day cycle for 6 cycles
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.
ITT analyses of vaginal bleeding patterns were based on all participants in the ITT group who had at least one evaluable cycle. Cycles were considered to be non-evaluable in case of insufficient bleeding data or improper cycle length. n= number of participants who had withdrawal bleeding/spotting for the respective cycle.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Measured Values

	NOMAC-E2	**DRSP-EE**
Number of Participants Analyzed [units: participants]	**30**	**16**
Average Number of Withdrawal Bleeding Days [units: Days] Mean (Standard Deviation)		
Cycle 1 (n=27 NOMAC-E2; n=16 DRSP-EE)	**7.2 (6.7)**	**7.0 (4.7)**
Cycle 1 (n=25 NOMAC-E2; n=16 DRSP-EE)	**7.4 (7.5)**	**5.0 (1.7)**
Cycle 3 (n=24 NOMAC-E2; n=15 DRSP-EE)	**4.3 (2.4)**	**5.4 (1.5)**
Cycle 4 (n=24 NOMAC-E2; n=15 DRSP-EE)	**4.7 (1.9)**	**5.3 (1.0)**
Cycle 5 (n=24 NOMAC-E2; n=15 DRSP-EE)	**5.5 (6.1)**	**4.9 (1.1)**
Cycle 6 (n=22 NOMAC-E2; n=13 DRSP-EE)	**5.2 (6.3)**	**3.9 (0.9)**

No statistical analysis provided for Average Number of Withdrawal Bleeding Days

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Serious Adverse Events

	NOMAC-E2	DRSP-EE
Total, serious adverse events		
# participants affected / at risk	**1/32 (3.13%)**	**0/16 (0.00%)**
Gastrointestinal disorders		
Appendicitis perforated [1]		
# participants affected / at risk	**1/32 (3.13%)**	**0/16 (0.00%)**
# events	**1**	**0**

1 Term from vocabulary, MedDRA (10.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
NOMAC-E2	Monophasic combined oral contraceptive (COC) tablets containing 2.5 mg Nomegestrol Acetate (NOMAC) and 1.5 mg Estradiol (E2) taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-24, active tablets; Days 25-28, placebo

	tablets) for 6 consecutive 28-day menstrual cycles.
DRSP-EE	Monophasic COC tablets containing 3 mg Drospirenone (DRSP) and 30 mcg Ethinyl Estradiol taken once daily from Day 1 of menstrual period up to and including Day 28 (Days 1-21, active tablets; Days 22-28, placebo tablets) for 6 consecutive 28-day menstrual cycles.

Other Adverse Events

	NOMAC-E2	DRSP-EE
Total, other (not including serious) adverse events		
# participants affected / at risk	**30/32 (93.75%)**	**15/16 (93.75%)**
Cardiac disorders		
Palpitations [1]		
# participants affected / at risk	**2/32 (6.25%)**	**0/16 (0.00%)**
# events	**2**	**0**
Eye disorders		
Conjunctivitis [1]		
# participants affected / at risk	**0/32 (0.00%)**	**2/16 (12.50%)**
# events	**0**	**2**
Gastrointestinal disorders		
Abdominal distension [1]		
# participants affected / at risk	**3/32 (9.38%)**	**0/16 (0.00%)**
# events	**3**	**0**
Abdominal pain [1]		
# participants affected / at risk	**3/32 (9.38%)**	**0/16 (0.00%)**
# events	**3**	**0**
Abdominal pain lower [1]		
# participants affected / at risk	**5/32 (15.63%)**	**3/16 (18.75%)**
# events	**6**	**4**
Constipation [1]		
# participants affected / at risk	**0/32 (0.00%)**	**1/16 (6.25%)**
# events	**0**	**1**
Diarrhoea [1]		
# participants affected / at risk	**11/32 (34.38%)**	**0/16 (0.00%)**
# events	**13**	**0**
Food poisoning [1]		
# participants affected / at risk	**0/32 (0.00%)**	**1/16 (6.25%)**
# events	**0**	**1**
Nausea [1]		
# participants affected / at risk	**8/32 (25.00%)**	**3/16 (18.75%)**
# events	**11**	**5**
Toothache [1]		
# participants affected / at risk	**3/32 (9.38%)**	**1/16 (6.25%)**
# events	**4**	**1**
Vomiting [1]		

# participants affected / at risk	2/32 (6.25%)	4/16 (25.00%)
# events	2	5
General disorders		
Fatigue [1]		
# participants affected / at risk	2/32 (6.25%)	1/16 (6.25%)
# events	2	1
Hangover [1]		
# participants affected / at risk	5/32 (15.63%)	1/16 (6.25%)
# events	7	1
Malaise [1]		
# participants affected / at risk	3/32 (9.38%)	1/16 (6.25%)
# events	3	1
Immune system disorders		
Hypersensitivity [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1
Infections and infestations		
Cystitis [1]		
# participants affected / at risk	4/32 (12.50%)	3/16 (18.75%)
# events	8	4
Gastroenteritis [1]		
# participants affected / at risk	3/32 (9.38%)	0/16 (0.00%)
# events	3	0
Influenza [1]		
# participants affected / at risk	5/32 (15.63%)	7/16 (43.75%)
# events	7	7
Nasopharyngitis [1]		
# participants affected / at risk	15/32 (46.88%)	9/16 (56.25%)
# events	23	12
Pyelonephritis [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1
Vaginal candidiasis [1]		
# participants affected / at risk	2/32 (6.25%)	1/16 (6.25%)
# events	2	1
Injury, poisoning and procedural complications		
Foreign body in eye [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1
Procedural pain [1]		
# participants affected / at risk	3/32 (9.38%)	0/16 (0.00%)
# events	3	0
Sunburn [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1

Investigations		
Weight decreased [1]		
# participants affected / at risk	**2/32 (6.25%)**	**0/16 (0.00%)**
# events	**2**	**0**
Weight increased [1]		
# participants affected / at risk	**4/32 (12.50%)**	**1/16 (6.25%)**
# events	**4**	**1**
Musculoskeletal and connective tissue disorders		
Arthralgia [1]		
# participants affected / at risk	**2/32 (6.25%)**	**1/16 (6.25%)**
# events	**3**	**1**
Back pain [1]		
# participants affected / at risk	**5/32 (15.63%)**	**1/16 (6.25%)**
# events	**8**	**2**
Nervous system disorders		
Dizziness [1]		
# participants affected / at risk	**3/32 (9.38%)**	**0/16 (0.00%)**
# events	**4**	**0**
Headache [1]		
# participants affected / at risk	**8/32 (25.00%)**	**4/16 (25.00%)**
# events	**17**	**7**
Psychiatric disorders		
Affect lability [1]		
# participants affected / at risk	**4/32 (12.50%)**	**1/16 (6.25%)**
# events	**4**	**1**
Depressed mood [1]		
# participants affected / at risk	**3/32 (9.38%)**	**0/16 (0.00%)**
# events	**3**	**0**
Renal and urinary disorders		
Dysuria [1]		
# participants affected / at risk	**0/32 (0.00%)**	**1/16 (6.25%)**
# events	**0**	**1**
Micturition urgency [1]		
# participants affected / at risk	**1/32 (3.13%)**	**1/16 (6.25%)**
# events	**1**	**1**
Reproductive system and breast disorders		
Breast enlargement [1]		
# participants affected / at risk	**1/32 (3.13%)**	**3/16 (18.75%)**
# events	**1**	**3**
Breast pain [1]		
# participants affected / at risk	**0/32 (0.00%)**	**4/16 (25.00%)**
# events	**0**	**7**
Breast tenderness [1]		
# participants affected / at risk	**2/32 (6.25%)**	**0/16 (0.00%)**

# events	2	0
Dysmenorrhoea [1]		
# participants affected / at risk	2/32 (6.25%)	1/16 (6.25%)
# events	2	1
Pelvic pain [1]		
# participants affected / at risk	3/32 (9.38%)	2/16 (12.50%)
# events	4	2
Vaginal discharge [1]		
# participants affected / at risk	2/32 (6.25%)	1/16 (6.25%)
# events	2	3
Vaginal odour [1]		
# participants affected / at risk	0/32 (0.00%)	2/16 (12.50%)
# events	0	2
Respiratory, thoracic and mediastinal disorders		
Pharyngolaryngeal pain [1]		
# participants affected / at risk	4/32 (12.50%)	1/16 (6.25%)
# events	5	1
Skin and subcutaneous tissue disorders		
Acne [1]		
# participants affected / at risk	6/32 (18.75%)	1/16 (6.25%)
# events	6	1
Dry skin [1]		
# participants affected / at risk	2/32 (6.25%)	0/16 (0.00%)
# events	2	0
Eczema [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	2
Hirsutism [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1
Pain of skin [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	2
Skin odour abnormal [1]		
# participants affected / at risk	0/32 (0.00%)	1/16 (6.25%)
# events	0	1
Vascular disorders		
Hot flush [1]		
# participants affected / at risk	2/32 (6.25%)	0/16 (0.00%)
# events	2	0

1 Term from vocabulary, MedDRA (10.1)

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:** The Sponsor recognizes the right of the investigator(s) to publish, but all publications must be based on data validated and released by the Sponsor. Any such scientific paper, presentation, or other communication concerning the clinical trial will first be submitted to the 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

Publications of Results:

Duijkers IJ, Klipping C, Grob P, Korver T. Effects of a monophasic combined oral contraceptive containing nomegestrol acetate and 17 beta-oestradiol on ovarian function in comparison to a monophasic combined oral contraceptive containing drospirenone and ethinylestradiol. Eur J Contracept Reprod Health Care. 2010 Oct;15(5):314-25. doi: 10.3109/13625187.2010.504313.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00511433 History of Changes
Other Study ID Numbers:	P05723 Organon protocol 292003
Study First Received:	August 2, 2007
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