ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CFEM345DDE09

Previous Study | Return to List | Next Study

Safety/Efficacy of Letrozole Monotherapy or in Combination With Zoledronic Acid as Extended Adjuvant Treatment of Postmenopausal Patients With Primary Breast Cancer

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00332709

First received: May 31, 2006
Last updated: October 10, 2011
Last verified: October 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: August 11, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Osteoporosis Postmenopausal
Interventions:	Drug: Letrozole Drug: Zoledronic acid

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
Total Randomized participants were 83. 2 patients were enrolled but never received study medication. Hence, 81 were included in the safety population.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Participant Flow: Overall Study

	Letrozole	Letrozole + Zoledronic Acid
STARTED	**40**	**41**
COMPLETED	**24**	**21**
NOT COMPLETED	**16**	**20**
Adverse Event	**11**	**14**
Withdrawal by Subject	**2**	**3**
Lost to Follow-up	**2**	**0**
Administrative Problems	**0**	**3**

Abnormal test procedure result	**1**	**0**

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
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months
Total	Total of all reporting groups

Baseline Measures

	Letrozole	Letrozole + Zoledronic Acid	Total
Number of Participants [units: participants]	**37**	**39**	**76**
Age [1] [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**37**	**39**	**76**
>=65 years	**0**	**0**	**0**

Age [units: years] Mean (Standard Deviation)	**61.3 (7.3)**	**58.4 (7.3)**	**59.8 (7.4)**
Gender [units: participants]			
Female	**37**	**39**	**76**
Male	**0**	**0**	**0**

[1] Demographic data is provided for the Intent to Treat population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Bone Mineral Density (BMD) From Baseline to Month 36 [Time Frame: at 36 months as compared to baseline]

Measure Type	Primary
Measure Title	Change in Bone Mineral Density (BMD) From Baseline to Month 36
Measure Description	Change in bone mineral density (BMD) measured by dual X-ray absorptiometry (DXA) in lumbar spine (L1-L4). Change calculated by (Month 36 BMD-Baseline BMD)/Baseline BMD*100.
Time Frame	at 36 months as compared to baseline
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in the analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	Letrozole + Zoledronic Acid
Number of Participants Analyzed [units: participants]	**21**	**20**
Change in Bone Mineral Density (BMD) From Baseline to Month 36 [units: Percent] Mean (Standard Deviation)	**-0.11 (0.14)**	**0.03 (0.08)**

No statistical analysis provided for Change in Bone Mineral Density (BMD) From Baseline to Month 36

2. Primary: Percent Change in Bone Mineral Density (BMD) From Baseline to Month 36 [Time Frame: Baseline, Month 36]

Measure Type	Primary
Measure Title	Percent Change in Bone Mineral Density (BMD) From Baseline to Month 36
Measure Description	Bone Mineral Density is measured by dual energy x-ray absorptiometry (DXA) scan. ANCOVA model was used in the analysis where: Variable = Baseline, Center, Treatment BMD = (Month 36 BMD-Baseline BMD)/Baseline BMD*100.
Time Frame	Baseline, Month 36
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in the analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**21**	**20**
Percent Change in Bone Mineral Density (BMD) From Baseline to Month 36 [units: Percent Change in BMD] Mean (Standard Deviation)	**-11.34 (17.72)**	**3.31 (8.32)**

No statistical analysis provided for Percent Change in Bone Mineral Density (BMD) From Baseline to Month 36

3. Primary: Change in T-score From Baseline to Month 36 [Time Frame: Baseline and Month 36]

Measure Type	Primary
Measure Title	Change in T-score From Baseline to Month 36
Measure Description	BMD measured by DXA (dual energy x-ray absorptiometry) at lumbar spine, L1-L4. The T-Score is a comparison of a patient's BMD to that of a healthy 30 year of the same sex and ethnicity. The criteria of the World Health Organization are Normal is a T-Score of 1.0 or higher. Osteopenia is defined as between - 1.0 and -2.5. Osteoporosis is defined as -2.5 or lower, meaning a bone density that is two and half standard deviations below the mean of a 30 year old

	man/woman.
Time Frame	Baseline and Month 36
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy.Participants with observations at both baseline and endpoint were included in the analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**20**	**21**
Change in T-score From Baseline to Month 36 [units: T-Score] Mean (Standard Deviation)	**-0.90 (1.03)**	**0.46 (0.27)**

No statistical analysis provided for Change in T-score From Baseline to Month 36

4. Primary: Change in Z Score From Baseline to Month 36 [Time Frame: Baseline, month 36]

Measure Type	Primary
Measure Title	Change in Z Score From Baseline to Month 36
Measure Description	Bone Mineral Density is measured by dual energy x-ray absorptiometry (DXA). The Z-Score is the number of standard deviations a patient's BMD differs from the average BMD of their age, sex and ethnicity. A Z-score of less than minus -1.5 raises concern of factors other than aging as contributing to osteoporosis.
Time Frame	Baseline, month 36
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in the analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**22**	**20**
Change in Z Score From Baseline to Month 36 [units: Z-Score] Mean (Standard Deviation)	**-0.31 (0.35)**	**0.25 (0.34)**

No statistical analysis provided for Change in Z Score From Baseline to Month 36

5. Secondary: Change in Bone Mineral Density From Baseline to 12 Months [Time Frame: Baseline, 12 months]

Measure Type	Secondary
Measure Title	Change in Bone Mineral Density From Baseline to 12 Months
Measure Description	Change in bone mineral density (BMD) measured by dual X-ray absorptiometry (DXA) in lumbar spine (L1-L4). Change calculated by (Month 36 BMD-Baseline BMD)/Baseline BMD*100.
Time Frame	Baseline, 12 months
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in the analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**23**	**23**
Change in Bone Mineral Density From Baseline to 12 Months		

[units: g/cm^2] **Mean (Standard Deviation)**	**-0.04 (0.04)**	**0.02 (0.05)**

No statistical analysis provided for Change in Bone Mineral Density From Baseline to 12 Months

6. Secondary: Number of Participants With Any Kind of Fractures, by Visit. [Time Frame: Baseline, Month 6, 12, 18, 24 , 30 and 36]

Measure Type	Secondary
Measure Title	Number of Participants With Any Kind of Fractures, by Visit.
Measure Description	Number of participants with fractures of any type since the last visit
Time Frame	Baseline, Month 6, 12, 18, 24 , 30 and 36
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations from baseline to month 36 were included in this analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**

Number of Participants Analyzed [units: participants]	**21**	**20**
Number of Participants With Any Kind of Fractures, by Visit. [units: Participants]		
Baseline	**0**	**0**
Month 6	**0**	**0**
Month 12	**0**	**0**
Month 18	**0**	**0**
Month 24	**0**	**0**
Month 30	**0**	**0**
Month 36	**0**	**0**

No statistical analysis provided for Number of Participants With Any Kind of Fractures, by Visit.

7. Secondary: Median Disease Free Survival (DFS) [Time Frame: 36 months]

Measure Type	Secondary
Measure Title	Median Disease Free Survival (DFS)
Measure Description	Disease Free Survival is measured in days and represents the number of days participants were progression free. Progression free survival is defined as the time from randomization to the date of the first documented progression or recurrence of disease or death from any cause. Median disease free survival is the time when 50% of the patients had a recurrence.
Time Frame	36 months
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. The median disease free survival was not observed because patients in the combination therapy did not have any recurrences.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**0**	**0**
Median Disease Free Survival (DFS) [units: Months] Median (95% Confidence Interval)		

No statistical analysis provided for Median Disease Free Survival (DFS)

8. Secondary: Change in T-Score From Baseline to Month 12 [Time Frame: Baseline, Month 12]

Measure Type	Secondary
Measure Title	Change in T-Score From Baseline to Month 12
Measure Description	BMD measured by DXA (dual energy x-ray absorptiometry) at lumbar spine, L1-L4. The T-Score is a comparison of a patient's BMD to that of a healthy 30 year of the same sex and ethnicity. The criteria of the World Health Organization are Normal is a T-Score of 1.0 or higher. Osteopenia is defined as between - 1.0 and -2.5. Osteoporosis is defined as

	-2.5 or lower, meaning a bone density that is two and half standard deviations below the mean of a 30 year old man/woman.
Time Frame	Baseline, Month 12
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in this analysis.

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**23**	**24**
Change in T-Score From Baseline to Month 12 [units: T-Score] Mean (Standard Deviation)	**-0.31 (0.35)**	**0.25 (0.34)**

No statistical analysis provided for Change in T-Score From Baseline to Month 12

9. Secondary: Change in Z-Score From Baseline to Month 12 [Time Frame: Baseline, Month 12]

Measure Type	Secondary
Measure Title	Change in Z-Score From Baseline to Month 12
Measure Description	(DXA). The Z-Score is the number of standard deviations a patient's BMD differs from the average BMD of their age, sex and ethnicity. A Z-score of less than minus -1.5 raises concern of factors other than aging as contributing to osteoporosis
Time Frame	Baseline, Month 12
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) The study population will consist of post menopausal breast cancer patients who have completed 4 to 6 years of adjuvant Tamoxifen therapy after therapy. Participants with observations at both baseline and endpoint were included in this analysis

Reporting Groups

	Description
Letrozole	Letrozole 2.5 mg/day for 3 years
Letrozole + Zoledronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Measured Values

	Letrozole	**Letrozole + Zoledronic Acid**
Number of Participants Analyzed [units: participants]	**23**	**22**
Change in Z-Score From Baseline to Month 12 [units: Z-Score] Mean (Standard Deviation)	**-0.26 (0.35)**	**0.37 (0.38)**

No statistical analysis provided for Change in Z-Score From Baseline to Month 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Letrozole	Letrozole orally 2.5 mg/day for 3 years
Letrozole + Zolendronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Serious Adverse Events

	Letrozole	Letrozole + Zolendronic Acid
Total, serious adverse events		
# participants affected / at risk	**6/40 (15.00%)**	**7/41 (17.07%)**
Cardiac disorders		
ACUTE MYOCARDIAL INFARCTION † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**
ANGINA PECTORIS † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**
ANGINA UNSTABLE † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**

CORONARY ARTERY STENOSIS † 1		
# participants affected / at risk	0/40 (0.00%)	1/41 (2.44%)
SUPRAVENTRICULAR TACHYCARDIA † 1		
# participants affected / at risk	0/40 (0.00%)	1/41 (2.44%)
Ear and labyrinth disorders		
VERTIGO POSITIONAL † 1		
# participants affected / at risk	1/40 (2.50%)	0/41 (0.00%)
General disorders		
CONCOMITANT DISEASE PROGRESSION † 1		
# participants affected / at risk	1/40 (2.50%)	0/41 (0.00%)
Hepatobiliary disorders		
CHOLECYSTITIS † 1		
# participants affected / at risk	1/40 (2.50%)	0/41 (0.00%)
Infections and infestations		
DIVERTICULITIS † 1		
# participants affected / at risk	0/40 (0.00%)	1/41 (2.44%)
Injury, poisoning and procedural complications		
CONTUSION † 1		
# participants affected / at risk	0/40 (0.00%)	1/41 (2.44%)
FALL † 1		
# participants affected / at risk	1/40 (2.50%)	0/41 (0.00%)
LOWER LIMB FRACTURE † 1		
# participants affected / at risk	1/40 (2.50%)	0/41 (0.00%)
ROAD TRAFFIC ACCIDENT † 1		
# participants affected / at risk	0/40 (0.00%)	1/41 (2.44%)

VASCULAR PSEUDOANEURYSM † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**
Investigations		
OXYGEN SATURATION DECREASED † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**
Musculoskeletal and connective tissue disorders		
AXILLARY MASS † 1		
# participants affected / at risk	**1/40 (2.50%)**	**0/41 (0.00%)**
COMPARTMENT SYNDROME † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**
OSTEOARTHRITIS † 1		
# participants affected / at risk	**1/40 (2.50%)**	**1/41 (2.44%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
METASTASES TO BONE † 1		
# participants affected / at risk	**1/40 (2.50%)**	**0/41 (0.00%)**
METASTASES TO LIVER † 1		
# participants affected / at risk	**1/40 (2.50%)**	**0/41 (0.00%)**
METASTASES TO LUNG † 1		
# participants affected / at risk	**1/40 (2.50%)**	**0/41 (0.00%)**
Reproductive system and breast disorders		
VAGINAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/40 (0.00%)**	**1/41 (2.44%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

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
Letrozole	Letrozole orally 2.5 mg/day for 3 years
Letrozole + Zolendronic Acid	Letrozole 2.5mg/day for 3 years plus Zoledronic acid 4mg every 6 months

Other Adverse Events

	Letrozole	Letrozole + Zolendronic Acid
Total, other (not including serious) adverse events		
# participants affected / at risk	**35/40 (87.50%)**	**35/41 (85.37%)**
Ear and labyrinth disorders		
VERTIGO † 1		
# participants affected / at risk	**2/40 (5.00%)**	**2/41 (4.88%)**
Gastrointestinal disorders		
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	**0/40 (0.00%)**	**4/41 (9.76%)**

CONSTIPATION † 1		
# participants affected / at risk	3/40 (7.50%)	0/41 (0.00%)
DIARRHOEA † 1		
# participants affected / at risk	2/40 (5.00%)	3/41 (7.32%)
DRY MOUTH † 1		
# participants affected / at risk	3/40 (7.50%)	3/41 (7.32%)
DYSPEPSIA † 1		
# participants affected / at risk	2/40 (5.00%)	1/41 (2.44%)
NAUSEA † 1		
# participants affected / at risk	0/40 (0.00%)	7/41 (17.07%)
General disorders		
CHILLS † 1		
# participants affected / at risk	1/40 (2.50%)	7/41 (17.07%)
FATIGUE † 1		
# participants affected / at risk	2/40 (5.00%)	12/41 (29.27%)
INFLUENZA LIKE ILLNESS † 1		
# participants affected / at risk	0/40 (0.00%)	3/41 (7.32%)
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	4/40 (10.00%)	3/41 (7.32%)
PYREXIA † 1		
# participants affected / at risk	0/40 (0.00%)	9/41 (21.95%)
Hepatobiliary disorders		
HEPATIC CYST † 1		
# participants affected / at risk	3/40 (7.50%)	0/41 (0.00%)
Infections and infestations		

CYSTITIS † 1		
# participants affected / at risk	2/40 (5.00%)	0/41 (0.00%)
NASOPHARYNGITIS † 1		
# participants affected / at risk	3/40 (7.50%)	4/41 (9.76%)
Metabolism and nutrition disorders		
DECREASED APPETITE † 1		
# participants affected / at risk	0/40 (0.00%)	3/41 (7.32%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	11/40 (27.50%)	14/41 (34.15%)
BACK PAIN † 1		
# participants affected / at risk	2/40 (5.00%)	5/41 (12.20%)
BONE PAIN † 1		
# participants affected / at risk	12/40 (30.00%)	14/41 (34.15%)
MUSCLE SPASMS † 1		
# participants affected / at risk	2/40 (5.00%)	0/41 (0.00%)
MUSCULOSKELETAL PAIN † 1		
# participants affected / at risk	0/40 (0.00%)	6/41 (14.63%)
MYALGIA † 1		
# participants affected / at risk	2/40 (5.00%)	2/41 (4.88%)
NECK PAIN † 1		
# participants affected / at risk	0/40 (0.00%)	5/41 (12.20%)
OSTEOARTHRITIS † 1		
# participants affected / at risk	2/40 (5.00%)	1/41 (2.44%)
OSTEOPENIA † 1		

# participants affected / at risk	5/40 (12.50%)	0/41 (0.00%)
PAIN IN EXTREMITY † 1		
# participants affected / at risk	5/40 (12.50%)	10/41 (24.39%)
SPINAL OSTEOARTHRITIS † 1		
# participants affected / at risk	2/40 (5.00%)	0/41 (0.00%)
Nervous system disorders		
HEADACHE † 1		
# participants affected / at risk	5/40 (12.50%)	9/41 (21.95%)
MIGRAINE † 1		
# participants affected / at risk	2/40 (5.00%)	1/41 (2.44%)
Psychiatric disorders		
DEPRESSION † 1		
# participants affected / at risk	2/40 (5.00%)	1/41 (2.44%)
SLEEP DISORDER † 1		
# participants affected / at risk	2/40 (5.00%)	3/41 (7.32%)
Reproductive system and breast disorders		
ATROPHIC VULVOVAGINITIS † 1		
# participants affected / at risk	3/40 (7.50%)	0/41 (0.00%)
VAGINAL DISCHARGE † 1		
# participants affected / at risk	2/40 (5.00%)	0/41 (0.00%)
Respiratory, thoracic and mediastinal disorders		
COUGH † 1		
# participants affected / at risk	2/40 (5.00%)	3/41 (7.32%)
DYSPNOEA † 1		

# participants affected / at risk	**0/40 (0.00%)**	**4/41 (9.76%)**
Skin and subcutaneous tissue disorders		
ALOPECIA † 1		
# participants affected / at risk	**6/40 (15.00%)**	**6/41 (14.63%)**
HYPERHIDROSIS † 1		
# participants affected / at risk	**1/40 (2.50%)**	**3/41 (7.32%)**
Vascular disorders		
HOT FLUSH † 1		
# participants affected / at risk	**9/40 (22.50%)**	**9/41 (21.95%)**
LYMPHOEDEMA † 1		
# participants affected / at risk	**2/40 (5.00%)**	**2/41 (4.88%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.X

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 terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial; or disclosure of the trial results in their entirety.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00332709 History of Changes
Other Study ID Numbers:	**CFEM345DDE09**
Study First Received:	May 31, 2006
Results First Received:	August 11, 2011
Last Updated:	October 10, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices