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Trial record **1 of 1** for: CFEM345D2407

Previous Study | Return to List | Next Study

A Study to Evaluate the Effect of Letrozole and Tamoxifen on Bone and Lipids in Postmenopausal Women With Breast Cancer

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Collaborators:
Danish Breast Cancer Cooperative Group
University of Sheffield

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00171704

First received: September 13, 2005
Last updated: May 1, 2012
Last verified: May 2012
History of Changes

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

Results First Received: February 27, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hormone Sensitive Resected Primary Breast Cancer in Postmenopausal Women.
Interventions:	Drug: Letrozole

	Drug: Tamoxifen

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
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	Tamoxifen 20 mg once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Participant Flow: Overall Study

	Letrozole	Tam-Let
STARTED	**133**	**130**
COMPLETED	**89**	**81**
NOT COMPLETED	**44**	**49**
Adverse Event	**24**	**33**
Disease Progression	**14**	**9**
New therapy for 2nd non-breast prim canc	**1**	**0**

Administrative Problems	**2**	**1**
Death	**2**	**2**
Withdrawal by Subject	**1**	**3**
Protocol Violation	**0**	**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
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	Tamoxifen 20 mg once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.
Total	Total of all reporting groups

Baseline Measures

	Letrozole	Tam-Let	Total
Number of Participants [units: participants]	**133**	**130**	**263**
Age [units: years] Mean (Standard Deviation)	**61.4 (6.1)**	**61.8 (6.2)**	**61.6 (6.2)**

Gender [units: participants]			
Female	133	130	263
Male	0	0	0

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine (L2-l4) [Time Frame: Baseline, 24 months]

Measure Type	Primary
Measure Title	Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine (L2-l4)
Measure Description	Lumbar spine (L2-L4) BMD measurements by dual energy X-ray absorptiometry (DXA) were performed after surgery and within 2 weeks prior to randomization and repeated every 6 months for the first 2 years and annually thereafter until 5 years after enrollment. The primary scanning site was the lumbar spine (L2 to L4) and the secondary scanning site was the total hip. All DXA scans were evaluated by a central reader.
Time Frame	Baseline, 24 months
Safety Issue	Yes

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 safety population consisted of only patients who took randomized therapy for at least one day. The number of patients in each treatment arm who had completed 2 years of the study and had centrally assessed measurements of lumbar spine or total hip BMD.

Reporting Groups

	Description

Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	Tam-Let
Number of Participants Analyzed [units: participants]	**63**	**68**
Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine (L2-l4) [units: Percent Change] Median (Full Range)	**-4.63 (-14.21 to 4.32)**	**0.37 (-6.98 to 15.21)**

No statistical analysis provided for Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine (L2-l4)

2. Secondary: Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine [Time Frame: Baseline, 60 months]

Measure Type	Secondary
Measure Title	Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine
Measure Description	Lumbar spine (L2-L4)BMD measurements by dual energy X-ray absorptiometry (DXA) were performed after surgery and within 2 weeks prior to randomization and repeated every 6 months for the first 2 years and annually thereafter until 5 years after enrollment. The primary scanning site was the lumbar spine (L2 to L4) and the secondary scanning site was the total hip. All DXA scans were evaluated by a central reader.
Time Frame	Baseline, 60 months
Safety Issue	Yes

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 safety population consisted of only patients who took randomized therapy for at least one day. The analysis at 5 years included all patients enrolled and who had centrally assessed measurements of lumbar spine and/or total hip BMD.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	Tam-Let
Number of Participants Analyzed [units: participants]	**56**	**53**
Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine [units: Percent change] Median (Full Range)	**-5.66 (-15.06 to 5.11)**	**-3.3 (-13.48 to 4.92)**

No statistical analysis provided for Percent Change From Baseline of Bone Mineral Density of the Lumbar Spine

3. Secondary: Percent Change From Baseline of Bone Mineral Density (BMD) of Total Hip [Time Frame: Baseline, 60 months]

Measure Type	Secondary
Measure Title	Percent Change From Baseline of Bone Mineral Density (BMD) of Total Hip
Measure Description	Total hip BMD measurements by dual energy X-ray absorptiometry (DXA) were performed after surgery and within 2 weeks prior to randomization and repeated every 6 months for the first 2 years and annually thereafter until 5 years after enrollment. All DXA scans were evaluated by a central reader.
Time Frame	Baseline, 60 months
Safety Issue	Yes

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 safety population consisted of only patients who took randomized therapy for at least one day. The analysis of BMD at 5 years included all patients enrolled with centrally assessed measurements of total hip BMD.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	**Tam-Let**
Number of Participants Analyzed [units: participants]	**62**	**65**
Percent Change From Baseline of Bone Mineral Density (BMD) of Total Hip [units: Percent Change] Median (Full Range)	**-5.77 (-22.53 to 12.53)**	**-3.98 (-13.6 to 5.57)**

No statistical analysis provided for Percent Change From Baseline of Bone Mineral Density (BMD) of Total Hip

4. Secondary: Median Percent Change From Baseline of Serum Markers of Bone Turnover [Time Frame: Baseline, 60 months]

Measure Type	Secondary
Measure Title	Median Percent Change From Baseline of Serum Markers of Bone Turnover
Measure Description	Bone turnover markers (fasting serum procollagen-I extension peptide [P1NP], C-telopeptide [CTX], skeletal bone-

	specific alkaline phosphatase [BSAP, N-telopeptide [NTX]) were measured at baseline/screening and at each visit thereafter. A central laboratory was used to analyze the samples. The analysis of bone markers was based on analysis of variance of the regression slopes calculated for each individual patient and each bone marker over time. In the following summary, only the median treatment group percent change from baseline (and range) at 5 years is presented for each bone marker.
Time Frame	Baseline, 60 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.
The safety population consisted of only patients who took randomized therapy for at least one day. During different time points, participants with observations at that time point were included in the analysis. The analysis of bone markers over time consisted of patients with measurements of specific markers at each time point.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	Tam-Let
Number of Participants Analyzed [units: participants]	**133**	**130**
Median Percent Change From Baseline of Serum Markers of Bone Turnover [units: Percent Change] Median (Full Range)		
Procollagen-I (PINP) (n=86, 78)	**-14.15 (-78.5 to 177.8)**	**-0.5 (-84.8 to 200)**

Bone Specific alkaline Phosphatase (n=87,78)	**16.2 (-53.6 to 192.6)**	**19.15 (-58.00 to 237.8)**
C-telopeptide (CTX) (n=88, 78)	**-12.05 (-80.9 to 130.6)**	**4.55 (-81.2 to 236.8)**
N-telopeptide (NTX) (n=-88, 77)	**-53.05 (-86.3 to 20.2)**	**-50.7 (-100 to 39)**

No statistical analysis provided for Median Percent Change From Baseline of Serum Markers of Bone Turnover

5. Secondary: Percentage Change From Baseline in Serum Lipids at 5 Years [Time Frame: Baseline, 60 months]

Measure Type	Secondary
Measure Title	Percentage Change From Baseline in Serum Lipids at 5 Years
Measure Description	Serum lipid profile (fasting serum cholesterol [total, HDL and calculated LDL], triglycerides, and lipoprotein [a]) were measured at baseline/screening and at each visit thereafter. A central laboratory was used to analyze the samples. The analysis of serum lipids was on the treatment group median percent change from baseline (and range) at 5 years.
Time Frame	Baseline, 60 months
Safety Issue	Yes

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 safety population consisted of only patients who took randomized therapy for at least one day. During different time points, participants with observations at that time point were included in the analysis.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years

Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	Tam-Let
Number of Participants Analyzed [units: participants]	**133**	**130**
Percentage Change From Baseline in Serum Lipids at 5 Years [units: Percent Change] Median (Full Range)		
Total Cholesterol (n=91, 82)	**-7.3 (-45.2 to 34.7)**	**-2.45 (-55.7 to 24.5)**
LDL Cholesterol (n=91, 82)	**-12.7 (-63.9 to 58.3)**	**-11.05 (-65 to 48.4)**
HDL Cholesterol (n=91, 82)	**8.7 (-40 to 60)**	**8.9 (-38.5 to 68.8)**

No statistical analysis provided for Percentage Change From Baseline in Serum Lipids at 5 Years

6. Secondary: Number of Participants With Clinically Relevant Changes From Baseline in Cholesterol [Time Frame: Baseline, 60 months]

Measure Type	Secondary
Measure Title	Number of Participants With Clinically Relevant Changes From Baseline in Cholesterol
Measure Description	Serum lipid profile (fasting serum cholesterol [total, HDL and calculated LDL], triglycerides, and lipoprotein [a]) were measured at baseline/screening and at each visit thereafter. A central laboratory was used to analyze the samples. Numbers are not additive, as patients could be included in multiple rows.
Time Frame	Baseline, 60 months
Safety Issue	Yes

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 safety population consisted of only patients who took randomized therapy for at least one day. The number of patients with pre-defined clinically relevant changes in serum lipids over the course of 5 years in each treatment arm is presented.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	**Tam-Let**
Number of Participants Analyzed [units: participants]	**133**	**130**
Number of Participants With Clinically Relevant Changes From Baseline in Cholesterol [units: Participants]		
Patients with one or more change	**30**	**21**
≥8 mmol/L total (T) cholesterol	**7**	**5**
≥7 mmol/L T.choles. & ≥1 risk for cardiac disease	**18**	**12**
≥6 mmol/L T. choles. & ≥2 risk for cardiac disease	**11**	**9**

No statistical analysis provided for Number of Participants With Clinically Relevant Changes From Baseline in Cholesterol

7. Secondary: Time to Disease Recurrence or Death [Time Frame: 60 months]

Measure Type	Secondary
Measure Title	Time to Disease Recurrence or Death
Measure Description	Disease-free survival was defined as the interval between randomization and earliest confirmed event of loco-regional recurrence, distant metastases, invasive contralateral breast cancer, or death from any cause.
Time Frame	60 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.
Analysis of disease-free survival was based on the ITT principle, with all enrolled (and randomized) patients included. The Kaplan-Meier product-limit approach was used.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	**Tam-Let**
Number of Participants Analyzed [units: participants]	**133**	**130**
Time to Disease Recurrence or Death [units: Days] Median (Inter-Quartile Range)	**NA** [1]	**NA** [1]

[1] Median time to disease recurrence or death was not achieved, nor was it possible to estimate 25% or 75th percentile for disease free survival.

No statistical analysis provided for Time to Disease Recurrence or Death

8. Secondary: Time to Overall Survival Events [Time Frame: 60 Months]

Measure Type	Secondary
Measure Title	Time to Overall Survival Events
Measure Description	Overall survival was measured from date of randomization to date of death.
Time Frame	60 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.
All randomized patients constituted the ITT Population, unless withdrawal of consent occurred after randomization but before the start of study treatment assigned.

Reporting Groups

	Description
Letrozole	2.5 mg once daily (q.d.)orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Measured Values

	Letrozole	**Tam-Let**
Number of Participants Analyzed [units: participants]	**133**	**130**
Time to Overall Survival Events		

[units: days] Median (Inter-Quartile Range)	**NA** [1]	**NA** [1]

[1] Median time to death was not achieved; nor was it possible to estimate 25th or 75th percentile for overall survival.

No statistical analysis provided for Time to Overall Survival Events

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Letrozole	2.5 mg once daily q.d. orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Serious Adverse Events

	Letrozole	Tam-Let
Total, serious adverse events		
# participants affected / at risk	**50/133 (37.59%)**	**41/130 (31.54%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**0/133 (0.00%)**	**2/130 (1.54%)**
Angina pectoris † 1		

# participants affected / at risk	1/133 (0.75%)	1/130 (0.77%)
Angina unstable † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Arrhythmia † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Atrial fibrillation † 1		
# participants affected / at risk	2/133 (1.50%)	2/130 (1.54%)
Atrial flutter † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Bundle branch block left † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Myocardial infarction † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Pericarditis † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Sinus bradycardia † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Endocrine disorders		
Goitre † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Eye disorders		
Retinal detachment † 1		
# participants affected / at risk	2/133 (1.50%)	0/130 (0.00%)
Gastrointestinal disorders		
Abdominal hernia † 1		

# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Abdominal pain † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Ascites † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Colitis † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Diarrhoea † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Diverticulum † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Pancreatitis acute † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Vomiting † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
General disorders		
Medical device complication † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Oedema peripheral † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Pyrexia † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Hepatobiliary disorders		
Cholelithiasis † 1		
# participants affected / at risk	1/133 (0.75%)	1/130 (0.77%)

Infections and infestations		
Breast infection † 1		
# participants affected / at risk	**0/133 (0.00%)**	**2/130 (1.54%)**
Bronchitis † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Cystitis † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Diverticulitis † 1		
# participants affected / at risk	**3/133 (2.26%)**	**0/130 (0.00%)**
Encephalitis herpes † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Erysipelas † 1		
# participants affected / at risk	**1/133 (0.75%)**	**2/130 (1.54%)**
Herpes zoster † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Infection † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Pneumonia † 1		
# participants affected / at risk	**4/133 (3.01%)**	**1/130 (0.77%)**
Skin infection † 1		
# participants affected / at risk	**2/133 (1.50%)**	**0/130 (0.00%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Injury, poisoning and procedural complications		
Ankle fracture † 1		

# participants affected / at risk	2/133 (1.50%)	1/130 (0.77%)
Femoral neck fracture † 1		
# participants affected / at risk	1/133 (0.75%)	1/130 (0.77%)
Femur fracture † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Humerus fracture † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Lower limb fracture † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Lumbar vertebral fracture † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Radius fracture † 1		
# participants affected / at risk	2/133 (1.50%)	1/130 (0.77%)
Rib fracture † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Spinal compression fracture † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Subdural haematoma † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Tendon rupture † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Traumatic haematoma † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Investigations		

Blood alkaline phosphatase increased † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Metabolism and nutrition disorders		
Hypovolaemia † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**0/133 (0.00%)**	**2/130 (1.54%)**
Arthritis † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Back pain † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Bone pain † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Intervertebral disc protrusion † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Osteoarthritis † 1		
# participants affected / at risk	**5/133 (3.76%)**	**4/130 (3.08%)**
Pain in extremity † 1		
# participants affected / at risk	**0/133 (0.00%)**	**2/130 (1.54%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Benign breast neoplasm † 1		

# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Benign salivary gland neoplasm † 1		
# participants affected / at risk	2/133 (1.50%)	0/130 (0.00%)
Breast cancer in situ † 1		
# participants affected / at risk	1/133 (0.75%)	1/130 (0.77%)
Cervix carcinoma † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Colon cancer † 1		
# participants affected / at risk	1/133 (0.75%)	2/130 (1.54%)
Gastrooesophageal cancer † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Hypopharyngeal cancer † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Lung neoplasm malignant † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Malignant melanoma † 1		
# participants affected / at risk	1/133 (0.75%)	2/130 (1.54%)
Malignant pleural effusion † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Metastases to bone † 1		
# participants affected / at risk	3/133 (2.26%)	0/130 (0.00%)
Metastases to lung † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Ovarian cancer † 1		
# participants affected / at risk	0/133 (0.00%)	2/130 (1.54%)

Thyroid adenoma † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Cerebrovascular accident † 1		
# participants affected / at risk	**0/133 (0.00%)**	**2/130 (1.54%)**
Dizziness † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Headache † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Renal and urinary disorders		
Calculus ureteric † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Reproductive system and breast disorders		
Colpocele † 1		
# participants affected / at risk	**2/133 (1.50%)**	**0/130 (0.00%)**
Cystocele † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Ovarian cyst † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Rectocele † 1		

# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Uterine polyp † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Uterine prolapse † 1		
# participants affected / at risk	1/133 (0.75%)	1/130 (0.77%)
Uterovaginal prolapse † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Vaginal haemorrhage † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Dyspnoea † 1		
# participants affected / at risk	2/133 (1.50%)	0/130 (0.00%)
Nasal polyps † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Pulmonary embolism † 1		
# participants affected / at risk	1/133 (0.75%)	2/130 (1.54%)
Skin and subcutaneous tissue disorders		
Scar † 1		
# participants affected / at risk	0/133 (0.00%)	1/130 (0.77%)
Skin irritation † 1		
# participants affected / at risk	1/133 (0.75%)	0/130 (0.00%)
Social circumstances		

Social problem † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Social stay hospitalisation † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Surgical and medical procedures		
Breast reconstruction † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	**1/133 (0.75%)**	**2/130 (1.54%)**
Hypotension † 1		
# participants affected / at risk	**0/133 (0.00%)**	**1/130 (0.77%)**
Orthostatic hypotension † 1		
# participants affected / at risk	**1/133 (0.75%)**	**0/130 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

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	2.5 mg once daily q.d. orally for 5 years
Tam-Let	20 mg Tamoxifen once daily (q.d.) orally for 2 years followed by Letrozole 2.5 mg q.d. orally for 3 years.

Other Adverse Events

	Letrozole	Tam-Let
Total, other (not including serious) adverse events		
# participants affected / at risk	**113/133 (84.96%)**	**110/130 (84.62%)**
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	**11/133 (8.27%)**	**6/130 (4.62%)**
Nausea † 1		
# participants affected / at risk	**14/133 (10.53%)**	**12/130 (9.23%)**
General disorders		
Fatigue † 1		
# participants affected / at risk	**7/133 (5.26%)**	**15/130 (11.54%)**
Oedema peripheral † 1		
# participants affected / at risk	**17/133 (12.78%)**	**15/130 (11.54%)**
Injury, poisoning and procedural complications		
Radiation skin injury † 1		
# participants affected / at risk	**6/133 (4.51%)**	**10/130 (7.69%)**
Investigations		
Weight decreased † 1		

# participants affected / at risk	6/133 (4.51%)	7/130 (5.38%)
Weight increased † 1		
# participants affected / at risk	5/133 (3.76%)	7/130 (5.38%)
Metabolism and nutrition disorders		
Hypercholesterolaemia † 1		
# participants affected / at risk	23/133 (17.29%)	21/130 (16.15%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	44/133 (33.08%)	43/130 (33.08%)
Back pain † 1		
# participants affected / at risk	14/133 (10.53%)	25/130 (19.23%)
Bone pain † 1		
# participants affected / at risk	16/133 (12.03%)	10/130 (7.69%)
Musculoskeletal pain † 1		
# participants affected / at risk	11/133 (8.27%)	8/130 (6.15%)
Myalgia † 1		
# participants affected / at risk	5/133 (3.76%)	12/130 (9.23%)
Osteopenia † 1		
# participants affected / at risk	15/133 (11.28%)	12/130 (9.23%)
Osteoporosis † 1		
# participants affected / at risk	21/133 (15.79%)	8/130 (6.15%)
Pain in extremity † 1		
# participants affected / at risk	13/133 (9.77%)	5/130 (3.85%)
Nervous system disorders		
Headache † 1		

# participants affected / at risk	3/133 (2.26%)	7/130 (5.38%)
Psychiatric disorders		
Depression † [1]		
# participants affected / at risk	6/133 (4.51%)	12/130 (9.23%)
Insomnia † [1]		
# participants affected / at risk	5/133 (3.76%)	8/130 (6.15%)
Reproductive system and breast disorders		
Vaginal discharge † [1]		
# participants affected / at risk	15/133 (11.28%)	12/130 (9.23%)
Vulvovaginal dryness † [1]		
# participants affected / at risk	10/133 (7.52%)	4/130 (3.08%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † [1]		
# participants affected / at risk	5/133 (3.76%)	8/130 (6.15%)
Skin and subcutaneous tissue disorders		
Alopecia † [1]		
# participants affected / at risk	7/133 (5.26%)	6/130 (4.62%)
Vascular disorders		
Hot flush † [1]		
# participants affected / at risk	13/133 (9.77%)	18/130 (13.85%)
Hypertension † [1]		
# participants affected / at risk	25/133 (18.80%)	17/130 (13.08%)
Lymphoedema † [1]		
# participants affected / at risk	7/133 (5.26%)	2/130 (1.54%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.0

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
The study was designed to investigate the effects of letrozole compared with tamoxifen for 2 years on BMD spine (L2-L4). The study was too small to investigate the comparative efficacy of treatments on disease-free survival or on overall survival.

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:** Principal Investigators are NOT employed by the organization sponsoring the study. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. 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 clinical trial.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00171704 History of Changes
Other Study ID Numbers:	**CFEM345D2407**
Study First Received:	September 13, 2005
Results First Received:	February 27, 2012
Last Updated:	May 1, 2012
Health Authority:	Denmark: Danish Medicines Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency