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The Efficacy and Safety of Pegylated Liposomal Doxorubicin Compared With Capecitabine as First Line Chemotherapy for Metastatic Breast Cancer (P04445/MK-2746-071)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Essex Pharma GmbH

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

ClinicalTrials.gov Identifier:
NCT00266799

First received: December 15, 2005
Last updated: February 6, 2015
Last verified: February 2015
History of Changes

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Purpose

This is an open-label, multinational, randomized, multicenter trial designed to compare pegylated liposomal doxorubicin with capecitabine as first line chemotherapy of metastatic breast cancer. The primary objective of the study is to compare the time to disease progression, although overall response rates, overall survival, quality of life, time to treatment failure, and safety and tolerability will also be assessed.

Condition	Intervention	Phase
Breast Cancer	Drug: Pegylated liposomal doxorubicin (SCH 200746) Drug: Capecitabine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized, Open-Label Trial Comparing Treatment With Either Pegylated Liposomal Doxorubicin or Capecitabine as First Line Chemotherapy for Metastatic Breast Cancer (PELICAN Trial)

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer Cancer

Drug Information available for: Doxorubicin Doxorubicin hydrochloride Capecitabine

U.S. FDA Resources

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

Primary Outcome Measures:

- Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death] [Designated as safety issue: No]

  TTP was defined as the time from onset of treatment with study drug until first evidence/diagnosis of progressive disease or - in the absence of any diagnosis of progressive disease - until the participant´s death. Diagnosis of progressive disease was done according to RECIST (Version 1.0) and/or investigator assessment based on RECIST. RECIST criteria used changes in the largest diameter of target/non-target lesions. Target (measurable) lesions were up to a maximum of 5 per organ & >20 mm by clinical imaging (>=10 mm with spiral CT scan). Non-target lesions were all other lesions.

Secondary Outcome Measures:

- Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death] [Designated as safety issue: No]

  Overall responses by investigator assessment/RECIST criteria of participant responses; CR=disappearance of target/nontarget lesions + PR=30% decrease in longest diameter sum (noting baseline sum) of target lesions. RECIST used changes in the largest diameter of target/non-target lesions. Target lesions were up to a maximum of 5 per organ & >20 mm by clinical imaging (>=10 mm with spiral CT scan). Non-target lesions were all other lesions. Evaluation of progress was repeated every 3 months (+/-7 days) post first date of lesion measurements, in detection absence until the participant´s death.

- Overall Survival Time in the PLD and Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until Death] [Designated as safety issue: No]

  Survival time was defined as duration time from onset of treatment with the study drug until death.

- Time to Treatment Failure in the PLD and the Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until End of Treatment] [Designated as safety issue: No]

  Time to treatment failure was defined as the duration of time from the date of the first administration of the study drug to the date of discontinuation of the study drug for any reason.

- Quality of Life (QoL) Measured by QoL Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) + Subjective Significance Questionnaire (SSQ)) [Time Frame: From Screening to Day 1 of every Treatment Cycle up to 12 Cycles] [Designated as safety issue: No]

  QoL questionnaire was an EORTC QLQ-C30 & SSQ integration. Scores on the SSQ scale ranged from 1 (very much worse) - 7 (very much better). SSQ consisted of 4 items which corresponded to core domains in the 30 Item EORTC QLQ-C30, such as improvement/deterioration in physical functioning, emotional functioning, social functioning, global QoL. Percentages were based on number of participants at each cycle & rounded to the nearest whole number. Early Withdrawal Questionnaires were obtained in 7-14 days of study drug final dose.

Enrollment:	210
Study Start Date:	January 2006
Study Completion Date:	October 2010
Primary Completion Date:	September 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Pegylated liposomal doxorubicin	Drug: Pegylated liposomal doxorubicin (SCH 200746) pegylated liposomal doxorubicin (50 mg/m^2 q 28 days) was administered intravenously until disease progression or unacceptable toxicity
Active Comparator: Capecitabine	Drug: Capecitabine capecitabine (1250 mg/m^2 BID x 14 days q 21 days) in tablets of 150 mg and 500 mg was administered orally, until disease progression or unacceptable toxicity

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients must be female.
- Patients must have metastatic disease of a cytological or histological confirmed breast cancer.
- Patients must be 18 years or older.
- Patients should have evaluable disease (at least uni-dimensionally measurable lesion according to the RECIST criteria in at least one site that has not been irradiated), however, patients who only have non-measurable/evaluable disease are not excluded. Also patients with only bone metastasis are not excluded.
- Patients must have an Eastern Cooperative Oncology Group (ECOG) 0-2.
- Patients must have a sufficient life expectancy to be treated with chemotherapy.
- Patients must be willing and able to complete study questionnaires.
- Patients must have adequate renal function as evidenced by serum creatinine <=1.5 mg/dL, or a creatinine clearance of >=45 mL/min (if serum creatinine is > 1.5 mg/dL but <= 1.8 mg/dL).
- Patients must have adequate bone marrow function as evidenced by leukocyte count greater than 3.5 g/L, hemoglobin >=9.0 g/dL, and platelet count >=100x10^9/L.
- Patients must have adequate liver function as evidenced by bilirubin of <=1.5 times the upper limits of normal (ULN) and alkaline phosphatase <=3 times, ULN unless related to liver metastasis.
- Patients must have Sodium and Potassium values within normal limits.
- Patients whose clinical condition (co-morbidity) allows a treatment with monotherapy or who expressed their wish to be treated with monotherapy.
- Patients must have signed an informed consent document indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study.

Exclusion Criteria:

- History of receiving prior chemotherapy in the metastatic setting (Note: patients may have had

hormonal therapy or chemotherapy in the adjuvant setting; patients may have received hormonal therapy in metastatic setting, patients may have received local radiotherapy).

- Patients with positive estrogen- / progesterone-receptor status, where an endocrine therapy is indicated. However, patients progressing under hormonal therapy are not excluded.
- Patients with known hypersensitivity to doxorubicinhydrochlorid or to any of the excipients OR known hypersensitivity to capecitabine or fluorouracil or to any of the excipients.
- Patients with known DPD (dihydro pyrimidine dehydrogenase) deficiency.
- Patients who are receiving a concomitant treatment with sorivudine or its chemically related analogues, such as brivudine.
- Patients who are taking concomitant medications (except bisphosphonates) for metastatic disease, including hormonal therapy, radiation therapy, trastuzumab, or biologicals are also not permitted.
- Patients with Human epidermal growth factor receptor 2 (Her-2/neu) overexpressing tumors with the most recent evaluation as the relevant result
  - immunologically Her2neu 3+ positive
  - Her2neu-2+ positive and ´Fluorescent in-situ hybridization (FISH)´ positive
- History of treatment with capecitabine
- History of treatment with anthracyclines in the adjuvant setting exceeding cumulative doses of anthracyclines by more than 360 mg/m^2 doxorubicin (or equivalents, i.e. 600mg/m^2 epirubicine).
- Patients with anthracycline resistant disease are not permitted. Anthracycline resistance is defined as development of locally recurrent or metastatic disease while on adjuvant anthracycline therapy, or relapse less than 12 months after completion of anthracycline therapy.
- Strong remission pressure that requires polychemotherapy with the exception of patients who are not suitable for a treatment with polychemotherapy or not accepting polychemotherapy.
- Evidence of primary or metastatic malignancy involving the central nervous system unless previously treated and asymptomatic for 3 months or greater.
- Patients with reduced liver functions (evidenced by bilirubin of above 1.5 times the upper limits of normal (ULN); alkaline phosphatase above 3

times ULN (except related to liver metastasis, in which case <=5 x ULN).

- Dyspnea on exertion.
- History of cardiac disease, with New York Heart Association Class II or greater, or clinical evidence of congestive heart failure or myocardial infarct within less than six months or an left ventricular ejection fraction (LVEF) below 50%.
- Woman with childbearing potential with insufficient contraception [e.g. intra-uterine device (IUD) are regarded as sufficient] during the study period and the six months following the last study drug application. All methods based on hormonal contraception are not permitted.
- Existing pregnancy or lactation (note on pregnancy test). A negative pregnancy test for women of childbearing potential has to be in place prior randomization (Note: A pregnancy test has to be done for patients who are not postmenopausal. Postmenopausal is defined as those not having a menstrual period for 12 months in a row).
- Existing doubts on ability and willingness of the subject for cooperation.
- Participation of the subject at a clinical study within the last 30 days.
- Participation of the subject in the same clinical study at an earlier date.
- Concomitant participation in another study than the one described here.
- Abuse of drugs, alcohol, or pharmaceuticals.
- Any condition, whether medical or non-medical, that may interfere, in the opinion of the investigator, with aim of this study.

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00266799 History of Changes
Other Study ID Numbers:	P04445
Study First Received:	December 15, 2005
Results First Received:	October 10, 2011
Last Updated:	February 6, 2015
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Additional relevant MeSH terms:

Breast Neoplasms	Antimetabolites
Breast Diseases	Antimetabolites, Antineoplastic
Neoplasms	Antineoplastic Agents
Neoplasms by Site	Enzyme Inhibitors
Skin Diseases	Molecular Mechanisms of Pharmacological Action
Capecitabine	Pharmacologic Actions
Doxorubicin	Therapeutic Uses
Liposomal doxorubicin	Topoisomerase II Inhibitors
Antibiotics, Antineoplastic	Topoisomerase Inhibitors

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: October 10, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Breast Cancer
Interventions:	Drug: Pegylated liposomal doxorubicin (SCH 200746) Drug: Capecitabine

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
210 participants were enrolled with 105 participants randomized for treatment with PLD and 105 participants randomized for treatment with Capecitabine, of which 7 participants in the PLD group and 3 participants in the Capecitabine group were not treated.

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
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Participant Flow: Overall Study

	Pegylated Liposomal Doxorubicin (PLD)	Capecitabine
STARTED	**98**	**102**
COMPLETED	**62**	**68**
NOT COMPLETED	**36**	**34**

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
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.
Total	Total of all reporting groups

Baseline Measures

	Pegylated Liposomal Doxorubicin (PLD)	Capecitabine	Total
Number of Participants [units: participants]	**105**	**105**	**210**
Age [1] [units: years] Mean (Standard Deviation)	**61.4 (10.66)**	**61.5 (10.59)**	**61.5 (10.60)**
Gender [1] [units: participants]			
Female	**105**	**105**	**210**
Male	**0**	**0**	**0**

[1] For baseline characteristics, all 210 participants who were enrolled and randomized were incorporated , although 7 participants in the PLD group and 3 participants in the Capecitabine group were not treated.

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death]

Measure Type	Primary
Measure Title	Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	TTP was defined as the time from onset of treatment with study drug until first evidence/diagnosis of progressive disease or – in the absence of any diagnosis of progressive disease – until the participant´s death. Diagnosis of progressive disease was done according to RECIST (Version 1.0) and/or investigator assessment based on RECIST. RECIST criteria used changes in the largest diameter of target/non-target lesions. Target (measurable) lesions were up to a maximum of 5 per organ & >20 mm by clinical imaging (>=10 mm with spiral CT scan). Non-target lesions were all other lesions.
Time Frame	From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death
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): 7 in PLD group & 3 participants in Capecitabine group were missing response assessments. TTP Population: included participants in view of major protocol violations/deviations, i.e. tumor-relevant inclusion/exclusion criteria, treatment compliance, tumor assessments by RECIST with maximum 4 month interval between assessments.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Measured Values

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**
Number of Participants Analyzed [units: participants]	**98**	**102**
Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST) [units: Months] Median (95% Confidence Interval)		
By Investigator Assessment (ITT)	**6.02 (5.10 to 8.19)**	**6.05 (4.27 to 9.07)**

By RECIST Criteria (ITT)	**6.58 (5.29 to 8.19)**	**7.10 (4.77 to 9.53)**
By Investigator Assessment (TTP N = 63, N = 59)	**5.85 (4.37 to 7.86)**	**5.88 (2.99 to 8.98)**
By RECIST Criteria (TTP N = 63, N = 59)	**6.02 (4.37 to 7.86)**	**6.05 (4.08 to 9.27)**

Statistical Analysis 1 for Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Log Rank
P Value [4]	0.6686
Hazard Ratio (HR) [5]	1.08
95% Confidence Interval	0.76 to 1.54

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By Investigator Assessment of ITT Population
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Non-inferiority was tested using the upper limit of the 95% CI for the hazard ratio as quantitative estimate of the minimum effect of PLD relative to capecitabine. Margin for non-inferiority was set to 1.143, reflecting an acceptable difference in TTP of 0.75 months assuming an expected median TTP of up to 6 months with the comparator. If the estimate was below margin, PLD was to be considered non-inferior to capecitabine assuming sufficient sensitivity to detect the drug effects of interest.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Log Rank
P Value [4]	0.4472

Hazard Ratio (HR) [5]	1.15
95% Confidence Interval	0.80 to 1.65

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By RECIST Criteria of ITT Population
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Non-inferiority was tested using the upper limit of the 95% CI for the hazard ratio as quantitative estimate of the minimum effect of PLD relative to capecitabine. Margin for non-inferiority was set to 1.143, reflecting an acceptable difference in TTP of 0.75 months assuming an expected median TTP of up to 6 months with the comparator. If the estimate was below margin, PLD was to be considered non-inferior to capecitabine assuming sufficient sensitivity to detect the drug effects of interest.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.5508
Hazard Ratio (HR) [4]	1.14
95% Confidence Interval	0.74 to 1.77

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By Investigator Assessment of TTP Population
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Time to Disease Progression (TTP) Using Response Evaluation Criteria in Solid Tumors (RECIST)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.4088

Hazard Ratio (HR) [4]	1.21
95% Confidence Interval	0.77 to 1.89

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By RECIST Criteria of TTP Population
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death]

Measure Type	Secondary
Measure Title	Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups
Measure Description	Overall responses by investigator assessment/RECIST criteria of participant responses; CR=disappearance of target/nontarget lesions + PR=30% decrease in longest diameter sum (noting baseline sum) of target lesions. RECIST used changes in the largest diameter of target/non-target lesions. Target lesions were up to a maximum of 5 per organ & >20 mm by clinical imaging (>=10 mm with spiral CT scan). Non-target lesions were all other lesions. Evaluation of progress was repeated every 3 months (+/-7 days) post first date of lesion measurements, in detection absence until the participant´s death.
Time Frame	From Day 1 (Cycle 1) until First Evidence/Diagnosis of Progressive Disease or Death
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) population included all randomized participants.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Measured Values

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**

Number of Participants Analyzed [units: participants]	**105**	**105**
Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups [units: Participants]		
By Investigator Assessment - CR	**1**	**0**
By Investigator Assessment - PR	**5**	**12**
By Investigator Assessment Overall Response	**6**	**12**
By RECIST Criteria - CR	**1**	**0**
By RECIST Criteria - PR	**8**	**11**
By RECIST Criteria Overall Response	**9**	**11**

Statistical Analysis 1 for Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.1726

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By Investigator Assessment
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Number of Participants With an Overall Response (Complete Response [CR] + Partial Response [PR]) Between PLD and Capecitabine Treatment Groups

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.6541

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	By RECIST Criteria
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Secondary: Overall Survival Time in the PLD and Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until Death]

Measure Type	Secondary
Measure Title	Overall Survival Time in the PLD and Capecitabine Treatment Groups
Measure Description	Survival time was defined as duration time from onset of treatment with the study drug until death.
Time Frame	From Day 1 (Cycle 1) until Death
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: 7 in PLD group and 3 participants in Capecitabine group were missing response assessments and therefore were not included in the analysis.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Measured Values

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**
Number of Participants Analyzed [units: participants]	**98**	**102**
Overall Survival Time in the PLD and Capecitabine Treatment Groups [units: Months] Median (95% Confidence Interval)	**23.31 (21.44 to 27.52)**	**26.79 (18.67 to 32.28)**

Statistical Analysis 1 for Overall Survival Time in the PLD and Capecitabine Treatment Groups

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.5265
Hazard Ratio (HR) [4]	1.12
95% Confidence Interval	0.79 to 1.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Time to Treatment Failure in the PLD and the Capecitabine Treatment Groups [Time Frame: From Day 1 (Cycle 1) until End of Treatment]

Measure Type	Secondary
Measure Title	Time to Treatment Failure in the PLD and the Capecitabine Treatment Groups
Measure Description	Time to treatment failure was defined as the duration of time from the date of the first administration of the study drug to the date of discontinuation of the study drug for any reason.
Time Frame	From Day 1 (Cycle 1) until End of Treatment
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: 7 in PLD group and 3 participants in Capecitabine group were missing response assessments and therefore were not included in the analysis.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Measured Values

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**
Number of Participants Analyzed [units: participants]	**98**	**102**
Time to Treatment Failure in the PLD and the Capecitabine Treatment Groups [units: Months] Median (95% Confidence Interval)	**4.60 (3.35 to 4.93)**	**3.68 (2.93 to 5.85)**

Statistical Analysis 1 for Time to Treatment Failure in the PLD and the Capecitabine Treatment Groups

Groups [1]	All groups
Method [2]	Log Rank

P Value [3]	0.0841
Hazard Ratio (HR) [4]	1.29

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	p-value also given for Hazard Ratio
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Quality of Life (QoL) Measured by QoL Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) + Subjective Significance Questionnaire (SSQ)) [Time Frame: From Screening to Day 1 of every Treatment Cycle up to 12 Cycles]

Measure Type	Secondary
Measure Title	Quality of Life (QoL) Measured by QoL Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) + Subjective Significance Questionnaire (SSQ))
Measure Description	QoL questionnaire was an EORTC QLQ-C30 & SSQ integration. Scores on the SSQ scale ranged from 1 (very much worse) - 7 (very much better). SSQ consisted of 4 items which corresponded to core domains in the 30 Item EORTC QLQ-C30, such as improvement/deterioration in physical functioning, emotional functioning, social functioning, global QoL. Percentages were based on number of participants at each cycle & rounded to the nearest whole number. Early Withdrawal Questionnaires were obtained in 7-14 days of study drug final dose.
Time Frame	From Screening to Day 1 of every Treatment Cycle up to 12 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: included all randomized participants. There were only a few participants who completed more than 12 cycles due to the longer duration of each cycle.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Measured Values

	Pegylated Liposomal	**Capecitabine**

	Doxorubicin (PLD)	
Number of Participants Analyzed [units: participants]	**105**	**105**
Quality of Life (QoL) Measured by QoL Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) + Subjective Significance Questionnaire (SSQ)) [units: Percentage of Participants]		
Screening - Very Much Worse	**4**	**14**
Screening - Moderately Worse	**8**	**14**
Screening - A Little Worse	**12**	**24**
Screening - About the Same	**67**	**41**
Screening - A Little Better	**4**	**0**
Screening - Moderately Better	**2**	**0**
Screening - Very Much Better	**2**	**7**
Cycle 1 - Very Much Worse	**0**	**9**
Cycle 1 - Moderately Worse	**10**	**9**
Cycle 1 - A Little Worse	**22**	**9**
Cycle 1 - About the Same	**63**	**65**
Cycle 1 - A Little Better	**5**	**2**
Cycle 1 - Moderately Better	**0**	**5**
Cycle 1 - Very Much Better	**0**	**0**
Cycle 2 - Very Much Worse	**3**	**11**
Cycle 2 - Moderately Worse	**9**	**8**
Cycle 2 - A Little Worse	**25**	**15**
Cycle 2 - About the Same	**51**	**50**
Cycle 2 - A Little Better	**9**	**9**
Cycle 2 - Moderately Better	**1**	**5**
Cycle 2 - Very Much Better	**1**	**3**
Cycle 3 - Very Much Worse	**4**	**3**
Cycle 3 - Moderately Worse	**13**	**13**
Cycle 3 - A Little Worse	**13**	**23**
Cycle 3 - About the Same	**58**	**48**
Cycle 3 - A Little Better	**8**	**10**
Cycle 3 - Moderately Better	**4**	**2**
Cycle 3 - Very Much Better	**0**	**0**
Cycle 4 - Very Much Worse	**4**	**6**
Cycle 4 - Moderately Worse	**11**	**12**
Cycle 4 - A Little Worse	**26**	**22**
Cycle 4 - About the Same	**47**	**55**
Cycle 4 - A Little Better	**9**	**2**

Cycle 4 - Moderately Better	**2**	**4**
Cycle 4 - Very Much Better	**0**	**0**
Cycle 5 - Very Much Worse	**5**	**0**
Cycle 5 - Moderately Worse	**0**	**2**
Cycle 5 - A Little Worse	**21**	**19**
Cycle 5 - About the Same	**40**	**62**
Cycle 5 - A Little Better	**19**	**14**
Cycle 5 - Moderately Better	**10**	**2**
Cycle 5 - Very Much Better	**5**	**0**
Cycle 6 - Very Much Worse	**5**	**3**
Cycle 6 - Moderately Worse	**7**	**6**
Cycle 6 - A Little Worse	**9**	**11**
Cycle 6 - About the Same	**58**	**60**
Cycle 6 - A Little Better	**14**	**14**
Cycle 6 - Moderately Better	**5**	**3**
Cycle 6 - Very Much Better	**2**	**3**
Cycle 7 - Very Much Worse	**0**	**3**
Cycle 7 - Moderately Worse	**4**	**3**
Cycle 7 - A Little Worse	**17**	**23**
Cycle 7 - About the Same	**52**	**42**
Cycle 7 - A Little Better	**13**	**6**
Cycle 7 - Moderately Better	**13**	**16**
Cycle 7 - Very Much Better	**0**	**6**
Cycle 8 - Very Much Worse	**0**	**3**
Cycle 8 - Moderately Worse	**13**	**6**
Cycle 8 - A Little Worse	**17**	**16**
Cycle 8 - About the Same	**57**	**61**
Cycle 8 - A Little Better	**9**	**6**
Cycle 8 - Moderately Better	**0**	**6**
Cycle 8 - Very Much Better	**4**	**0**
Cycle 9 - Very Much Worse	**6**	**0**
Cycle 9 - Moderately Worse	**0**	**3**
Cycle 9 - A Little Worse	**25**	**21**
Cycle 9 - About the Same	**50**	**55**
Cycle 9 - A Little Better	**6**	**10**
Cycle 9 - Moderately Better	**6**	**3**
Cycle 9 - Very Much Better	**6**	**7**
Cycle 10 - Very Much Worse	**0**	**4**

Cycle 10 - Moderately Worse	**8**	**8**
Cycle 10 - A Little Worse	**17**	**13**
Cycle 10 - About the Same	**67**	**50**
Cycle 10 - A Little Better	**8**	**13**
Cycle 10 - Moderately Better	**0**	**4**
Cycle 10 - Very Much Better	**0**	**8**
Cycle 11 - Very Much Worse	**0**	**0**
Cycle 11 - Moderately Worse	**11**	**9**
Cycle 11 - A Little Worse	**0**	**13**
Cycle 11 - About the Same	**67**	**39**
Cycle 11 - A Little Better	**11**	**13**
Cycle 11 - Moderately Better	**11**	**9**
Cycle 11 - Very Much Better	**0**	**17**
Cycle 12 - Very Much Worse	**0**	**4**
Cycle 12 - Moderately Worse	**0**	**8**
Cycle 12 - A Little Worse	**11**	**13**
Cycle 12 - About the Same	**78**	**50**
Cycle 12 - A Little Better	**11**	**13**
Cycle 12 - Moderately Better	**0**	**8**
Cycle 12 - Very Much Better	**0**	**4**

No statistical analysis provided for Quality of Life (QoL) Measured by QoL Questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) + Subjective Significance Questionnaire (SSQ))

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Due to the specification of no reason for the 2 deaths on the Capecitabine arm, these 2 events were coded as 'Death'.

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Serious Adverse Events

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**

Total, serious adverse events		
# participants affected / at risk	**30/98 (30.61%)**	**46/102 (45.10%)**
Blood and lymphatic system disorders		
NEUTROPENIA † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
Cardiac disorders		
ATRIAL FIBRILLATION † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
CARDIAC FAILURE † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**2**	**0**
TACHYCARDIA † 1		
# participants affected / at risk	**0/98 (0.00%)**	**2/102 (1.96%)**
# events	**0**	**2**
Ear and labyrinth disorders		
ACUTE VESTIBULAR SYNDROME † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
VERTIGO † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
Gastrointestinal disorders		
ABDOMINAL PAIN † 1		
# participants affected / at risk	**0/98 (0.00%)**	**2/102 (1.96%)**
# events	**0**	**2**
COLITIS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
DIARRHOEA † 1		
# participants affected / at risk	**2/98 (2.04%)**	**8/102 (7.84%)**
# events	**2**	**8**
FEMORAL HERNIA † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
HAEMATEMESIS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
ILEUS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**

NAUSEA † 1		
# participants affected / at risk	**0/98 (0.00%)**	**2/102 (1.96%)**
# events	**0**	**2**
STOMATITIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**2/102 (1.96%)**
# events	**1**	**2**
VOMITING † 1		
# participants affected / at risk	**0/98 (0.00%)**	**2/102 (1.96%)**
# events	**0**	**2**
General disorders		
ASTHENIA † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
CATHETER THROMBOSIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
CONDITION AGGRAVATED † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
DEATH † 1		
# participants affected / at risk	**0/98 (0.00%)**	**2/102 (1.96%)**
# events	**0**	**2**
DISEASE PROGRESSION † 1		
# participants affected / at risk	**0/98 (0.00%)**	**3/102 (2.94%)**
# events	**0**	**3**
FATIGUE † 1		
# participants affected / at risk	**2/98 (2.04%)**	**3/102 (2.94%)**
# events	**2**	**4**
GENERAL PHYSICAL HEALTH DETERIORATION † 1		
# participants affected / at risk	**4/98 (4.08%)**	**2/102 (1.96%)**
# events	**4**	**2**
PYREXIA † 1		
# participants affected / at risk	**0/98 (0.00%)**	**3/102 (2.94%)**
# events	**0**	**3**
Hepatobiliary disorders		
HEPATIC FAILURE † 1		
# participants affected / at risk	**1/98 (1.02%)**	**1/102 (0.98%)**
# events	**1**	**2**
SUBACUTE HEPATIC FAILURE † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**2**
Immune system disorders		
HYPERSENSITIVITY † 1		
# participants affected / at risk	**2/98 (2.04%)**	**0/102 (0.00%)**
# events	**2**	**0**

Infections and infestations		
CATHETER SITE INFECTION † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
FOLLICULITIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
HERPES ZOSTER † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
LARYNGITIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
PNEUMONIA † 1		
# participants affected / at risk	**1/98 (1.02%)**	**1/102 (0.98%)**
# events	**1**	**1**
PSEUDOMONAS INFECTION † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
PYELONEPHRITIS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
SEPSIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
UROSEPSIS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
WOUND INFECTION † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
WOUND INFECTION BACTERIAL † 1		
# participants affected / at risk	**1/98 (1.02%)**	**0/102 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
FEMORAL NECK FRACTURE † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
FOOT FRACTURE † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
FRACTURE † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
POST PROCEDURAL HAEMORRHAGE † 1		

# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
RADIUS FRACTURE † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
TRACHEAL OBSTRUCTION † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
VASCULAR ACCESS COMPLICATION † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
Investigations		
ASPARTATE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
BLOOD POTASSIUM DECREASED † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
BLOOD POTASSIUM INCREASED † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
EAR, NOSE AND THROAT EXAMINATION ABNORMAL † 1		
# participants affected / at risk	2/98 (2.04%)	0/102 (0.00%)
# events	2	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
HAEMOGLOBIN DECREASED † 1		
# participants affected / at risk	1/98 (1.02%)	4/102 (3.92%)
# events	3	4
NEUTROPHIL COUNT DECREASED † 1		
# participants affected / at risk	2/98 (2.04%)	1/102 (0.98%)
# events	2	1
WHITE BLOOD CELL COUNT DECREASED † 1		
# participants affected / at risk	2/98 (2.04%)	1/102 (0.98%)
# events	2	1
Musculoskeletal and connective tissue disorders		
BACK PAIN † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
BONE PAIN † 1		
# participants affected / at risk	1/98 (1.02%)	2/102 (1.96%)
# events	1	2
INTERVERTEBRAL DISC PROTRUSION † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)

# events	0	1
MUSCULOSKELETAL CHEST PAIN † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
PATHOLOGICAL FRACTURE † 1		
# participants affected / at risk	0/98 (0.00%)	2/102 (1.96%)
# events	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
CONTRALATERAL BREAST CANCER † 1		
# participants affected / at risk	1/98 (1.02%)	1/102 (0.98%)
# events	1	1
MALIGNANT PLEURAL EFFUSION † 1		
# participants affected / at risk	2/98 (2.04%)	3/102 (2.94%)
# events	2	3
METASTASES TO ABDOMINAL WALL † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
METASTASES TO LYMPH NODES † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
METASTASES TO MENINGES † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
METASTASES TO THORAX † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
PERICARDIAL EFFUSION MALIGNANT † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
TUMOUR PAIN † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
Nervous system disorders		
DIZZINESS † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
ENCEPHALOPATHY † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
FACIAL PALSY † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
HEADACHE † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)

# events	1	0
SYNCOPE † 1		
# participants affected / at risk	0/98 (0.00%)	2/102 (1.96%)
# events	0	2
VERTIGO CNS ORIGIN † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
VITH NERVE PARALYSIS † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
Psychiatric disorders		
SUICIDAL IDEATION † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
Renal and urinary disorders		
RENAL FAILURE † 1		
# participants affected / at risk	0/98 (0.00%)	3/102 (2.94%)
# events	0	3
URINARY INCONTINENCE † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
Reproductive system and breast disorders		
BREAST PAIN † 1		
# participants affected / at risk	1/98 (1.02%)	1/102 (0.98%)
# events	1	1
Respiratory, thoracic and mediastinal disorders		
ACQUIRED TRACHEO-OESOPHAGEAL FISTULA † 1		
# participants affected / at risk	0/98 (0.00%)	1/102 (0.98%)
# events	0	1
DYSPNOEA † 1		
# participants affected / at risk	2/98 (2.04%)	5/102 (4.90%)
# events	3	7
HAEMOPTYSIS † 1		
# participants affected / at risk	1/98 (1.02%)	0/102 (0.00%)
# events	1	0
PLEURAL EFFUSION † 1		
# participants affected / at risk	2/98 (2.04%)	2/102 (1.96%)
# events	2	3
PNEUMOTHORAX † 1		
# participants affected / at risk	1/98 (1.02%)	2/102 (1.96%)
# events	1	2
PULMONARY EMBOLISM † 1		
# participants affected / at risk	0/98 (0.00%)	6/102 (5.88%)
# events	0	6
Skin and subcutaneous tissue disorders		

PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME † 1		
# participants affected / at risk	**1/98 (1.02%)**	**4/102 (3.92%)**
# events	**1**	**4**
Vascular disorders		
DEEP VEIN THROMBOSIS † 1		
# participants affected / at risk	**0/98 (0.00%)**	**1/102 (0.98%)**
# events	**0**	**1**
THROMBOSIS † 1		
# participants affected / at risk	**1/98 (1.02%)**	**3/102 (2.94%)**
# events	**1**	**3**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Due to the specification of no reason for the 2 deaths on the Capecitabine arm, these 2 events were coded as 'Death'.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Pegylated Liposomal Doxorubicin (PLD)	PLD 50 mg/m^2 was administered intravenously once every 28 days. Each cycle was repeated until progress or unacceptable toxicity.
Capecitabine	Capecitabine 1250 mg/m^2, in tablets of 150 mg and 500 mg, was administered orally twice daily (BID) for 14 consecutive days followed by a 7-day rest period. Each cycle was repeated every 21 days until progress or unacceptable toxicity.

Other Adverse Events

	Pegylated Liposomal Doxorubicin (PLD)	**Capecitabine**
Total, other (not including serious) adverse events		
# participants affected / at risk	**96/98 (97.96%)**	**98/102 (96.08%)**
Ear and labyrinth disorders		
VERTIGO † 1		
# participants affected / at risk	**5/98 (5.10%)**	**2/102 (1.96%)**
# events	**6**	**2**
Eye disorders		
LACRIMATION INCREASED † 1		

# participants affected / at risk	0/98 (0.00%)	7/102 (6.86%)
# events	0	7
Gastrointestinal disorders		
ABDOMINAL PAIN † 1		
# participants affected / at risk	1/98 (1.02%)	11/102 (10.78%)
# events	1	14
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	5/98 (5.10%)	9/102 (8.82%)
# events	5	11
CONSTIPATION † 1		
# participants affected / at risk	25/98 (25.51%)	10/102 (9.80%)
# events	43	11
DIARRHOEA † 1		
# participants affected / at risk	14/98 (14.29%)	42/102 (41.18%)
# events	18	82
DYSPEPSIA † 1		
# participants affected / at risk	7/98 (7.14%)	9/102 (8.82%)
# events	7	13
DYSPHAGIA † 1		
# participants affected / at risk	7/98 (7.14%)	1/102 (0.98%)
# events	8	1
NAUSEA † 1		
# participants affected / at risk	41/98 (41.84%)	41/102 (40.20%)
# events	58	57
OESOPHAGITIS † 1		
# participants affected / at risk	5/98 (5.10%)	0/102 (0.00%)
# events	6	0
STOMATITIS † 1		
# participants affected / at risk	39/98 (39.80%)	17/102 (16.67%)
# events	53	22
VOMITING † 1		
# participants affected / at risk	18/98 (18.37%)	28/102 (27.45%)
# events	24	41
General disorders		
FATIGUE † 1		
# participants affected / at risk	53/98 (54.08%)	54/102 (52.94%)
# events	81	89
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	7/98 (7.14%)	12/102 (11.76%)
# events	7	12
PYREXIA † 1		
# participants affected / at risk	5/98 (5.10%)	6/102 (5.88%)
# events	5	9
Immune system disorders		
HYPERSENSITIVITY † 1		

# participants affected / at risk	10/98 (10.20%)	1/102 (0.98%)
# events	12	1
Infections and infestations		
NASOPHARYNGITIS † 1		
# participants affected / at risk	4/98 (4.08%)	8/102 (7.84%)
# events	5	11
Investigations		
ALANINE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	10/98 (10.20%)	15/102 (14.71%)
# events	12	23
ASPARTATE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	11/98 (11.22%)	12/102 (11.76%)
# events	14	22
BLOOD ALKALINE PHOSPHATASE INCREASED † 1		
# participants affected / at risk	8/98 (8.16%)	6/102 (5.88%)
# events	10	9
BLOOD BILIRUBIN INCREASED † 1		
# participants affected / at risk	2/98 (2.04%)	13/102 (12.75%)
# events	3	38
BLOOD CREATININE INCREASED † 1		
# participants affected / at risk	3/98 (3.06%)	8/102 (7.84%)
# events	3	11
EAR, NOSE AND THROAT EXAMINATION ABNORMAL † 1		
# participants affected / at risk	42/98 (42.86%)	17/102 (16.67%)
# events	57	21
GAMMA-GLUTAMYLTRANSFERASE INCREASED † 1		
# participants affected / at risk	8/98 (8.16%)	2/102 (1.96%)
# events	11	2
HAEMOGLOBIN DECREASED † 1		
# participants affected / at risk	25/98 (25.51%)	19/102 (18.63%)
# events	50	41
NEUTROPHIL COUNT DECREASED † 1		
# participants affected / at risk	18/98 (18.37%)	9/102 (8.82%)
# events	55	20
PLATELET COUNT DECREASED † 1		
# participants affected / at risk	6/98 (6.12%)	7/102 (6.86%)
# events	10	12
WEIGHT DECREASED † 1		
# participants affected / at risk	5/98 (5.10%)	7/102 (6.86%)
# events	7	8
WHITE BLOOD CELL COUNT DECREASED † 1		
# participants affected / at risk	37/98 (37.76%)	16/102 (15.69%)
# events	106	37
Metabolism and nutrition disorders		
ANOREXIA † 1		

# participants affected / at risk	12/98 (12.24%)	15/102 (14.71%)
# events	13	18
Musculoskeletal and connective tissue disorders		
BACK PAIN † 1		
# participants affected / at risk	13/98 (13.27%)	10/102 (9.80%)
# events	18	10
BONE PAIN † 1		
# participants affected / at risk	9/98 (9.18%)	15/102 (14.71%)
# events	13	18
PAIN IN EXTREMITY † 1		
# participants affected / at risk	8/98 (8.16%)	3/102 (2.94%)
# events	11	12
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
TUMOUR PAIN † 1		
# participants affected / at risk	6/98 (6.12%)	2/102 (1.96%)
# events	8	4
Nervous system disorders		
DIZZINESS † 1		
# participants affected / at risk	3/98 (3.06%)	10/102 (9.80%)
# events	3	15
DYSGEUSIA † 1		
# participants affected / at risk	2/98 (2.04%)	8/102 (7.84%)
# events	2	10
HEADACHE † 1		
# participants affected / at risk	6/98 (6.12%)	5/102 (4.90%)
# events	6	5
PERIPHERAL SENSORY NEUROPATHY † 1		
# participants affected / at risk	17/98 (17.35%)	25/102 (24.51%)
# events	23	29
Psychiatric disorders		
DEPRESSION † 1		
# participants affected / at risk	2/98 (2.04%)	8/102 (7.84%)
# events	2	9
INSOMNIA † 1		
# participants affected / at risk	9/98 (9.18%)	7/102 (6.86%)
# events	10	9
Respiratory, thoracic and mediastinal disorders		
COUGH † 1		
# participants affected / at risk	5/98 (5.10%)	11/102 (10.78%)
# events	5	12
DYSPNOEA † 1		
# participants affected / at risk	14/98 (14.29%)	22/102 (21.57%)
# events	19	26
Skin and subcutaneous tissue disorders		

ALOPECIA † 1		
# participants affected / at risk	**27/98 (27.55%)**	**10/102 (9.80%)**
# events	**27**	**11**
DRY SKIN † 1		
# participants affected / at risk	**10/98 (10.20%)**	**6/102 (5.88%)**
# events	**11**	**6**
EXFOLIATIVE RASH † 1		
# participants affected / at risk	**7/98 (7.14%)**	**7/102 (6.86%)**
# events	**8**	**8**
HYPERHIDROSIS † 1		
# participants affected / at risk	**8/98 (8.16%)**	**3/102 (2.94%)**
# events	**12**	**4**
NAIL DISORDER † 1		
# participants affected / at risk	**9/98 (9.18%)**	**12/102 (11.76%)**
# events	**12**	**16**
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME † 1		
# participants affected / at risk	**65/98 (66.33%)**	**68/102 (66.67%)**
# events	**227**	**248**
PRURITUS † 1		
# participants affected / at risk	**8/98 (8.16%)**	**2/102 (1.96%)**
# events	**11**	**2**
SKIN HYPERPIGMENTATION † 1		
# participants affected / at risk	**6/98 (6.12%)**	**3/102 (2.94%)**
# events	**9**	**3**
Vascular disorders		
FLUSHING † 1		
# participants affected / at risk	**6/98 (6.12%)**	**2/102 (1.96%)**
# events	**7**	**3**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

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

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:** If investigator wishes to publish study information, a copy of the manuscript must be provided to sponsor for review at least 60 days before submission of publication/presentation. In the event issues arise regarding scientific integrity/regulatory compliance, sponsor will review these issues with investigator. Investigator will not publish data derived from the individual site until 12 months after conclusion/abandonment/termination of study at all sites.

Results Point of Contact:

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00266799 History of Changes
Other Study ID Numbers:	P04445
Study First Received:	December 15, 2005
Results First Received:	October 10, 2011
Last Updated:	February 6, 2015
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

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