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ClinicalTrials.gov ID: NCT00077857

Study Identification

Unique Protocol ID:	NO16853
Brief Title:	A Study to Assess Capecitabine (Xeloda®) in Patients With Locally Advanced or Metastatic Breast Cancer
Official Title:	A Randomized, Open-label Study of the Effect of Different Dosing Regimens of Xeloda® in Combination With Taxotere® on Disease Progression in Patients With Locally Advanced and/or Metastatic Breast Cancer
Secondary IDs:	

Study Status

Record Verification:	March 2013
Overall Status:	Completed
Study Start:	July 2003 []
Primary Completion:	March 2010 [Actual]
Study Completion:	March 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 45,305 Serial Number: S-481 Has Expanded Access: No
Human Subjects Review:	Board Status: Approved
Data Monitoring:	
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	This 2 arm study compared the efficacy and safety of label dose of capecitabine (Xeloda®) to that of a lower dose of Xeloda® plus docetaxel (Taxotere®) in patients with locally advanced or metastatic breast cancer after failure of chemotherapy with an anthracycline. Patients were randomized to receive either 1250 mg/m^2 or 825 mg/m^2 orally twice a day (po bid) on days 1-14 of each 3 week cycle, in combination with Taxotere® 75 mg/m2 intravenous (iv) on day 1 of each 3 week cycle. The anticipated time on study treatment was until disease progression and the target sample size was 440 individuals.
Detailed Description:	

Conditions

Conditions:	Breast Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)

Allocation:	Randomized
Enrollment:	470 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1250 mg/m^2 capecitabine + docetaxel 1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.	Drug: capecitabine (Xeloda®) 825 mg/m^2 or 1250 mg/m2 orally twice a day on days 1 to 14 of each 3 week cycle. Other Names: • Xeloda® Drug: docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle Other Names: • Taxotere®
Experimental: 825 mg/m^2 capecitabine + docetaxel 825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.	Drug: capecitabine (Xeloda®) 825 mg/m^2 or 1250 mg/m2 orally twice a day on days 1 to 14 of each 3 week cycle. Other Names: • Xeloda® Drug: docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle Other Names: • Taxotere®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	Female
Gender Based:	
Accepts Healthy Volunteers:	No

Criteria: Inclusion Criteria:

- women >=18 years of age;
- >=1 target lesion;
- locally advanced or metastatic breast cancer;
- demonstrated resistance to anthracycline;
- >=2 regimens of chemotherapy for advanced/metastatic disease.

Exclusion Criteria:

- previous treatment with Xeloda, continuous 5-fluorouracil infusion, or other oral fluoropyrimidines;
- previous treatment with paclitaxel or docetaxel for advanced/metastatic disease.

Contacts/Locations

Central Contact Person: Please reference Study ID Number: NO16853 www.roche.com/about_roche/roche_worldwide.htm
Telephone: 888-662-6728 (U.S. Only)
Email: genentechclinicaltrials@druginfo.com

Central Contact Backup:

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: **United States, Virginia**
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United States, Texas
Austin, Texas, United States, 78705

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Kingston, Pennsylvania, United States, 18704

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Berkeley, California, United States, 94704

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Hoover, Alabama, United States, 35216

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Tucson, Arizona, United States, 85715

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Saint Joseph, Missouri, United States, 64507

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Birmingham, Alabama, United States, 35233

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Knoxville, Tennessee, United States, 37920

United States, Louisiana
Houma, Louisiana, United States, 70360

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Collierville, Tennessee, United States, 38017

United States, Florida
Port Saint Lucie, Florida, United States, 34952

Tamarac, Florida, United States, 33321

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Colchester, Vermont, United States, 05446

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POZNAN, Poland, 61-878

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BANGKOK, Thailand, 10400

KHON KAEN, Thailand, 40002

South Africa

DURBAN, South Africa, 4001

BLOEMFONTEIN, South Africa, 9301

POLOKWANE, South Africa, 0699

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SARAJEVO, Bosnia and Herzegovina, 71000

MOSTAR, Bosnia and Herzegovina, 88000

TUZLA, Bosnia and Herzegovina, 75000

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TRIVANDRUM, India, 695 011

HYDERABAD, India, 500 082

BANGALORE, India, 560027

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HYDERABAD, India, 500 033

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IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Overall Study

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Started	235	235
Received Study Drug	231	234
Safety Population: Actual Dose Received	217 [1]	248
Completed	34	31
Not Completed	201	204

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Adverse Event	30	32
Death	7	3
Insufficient therapeutic response	112	128
Violation of selection criteria at entry	3	1
Other protocol violation	0	1
Refused treatment	29	21
Failure to return	5	5
Other	15	13

[1] 14 patients in the 1250 dose arm received a lower dose and were included in the 825 arm for Safety.

Baseline Characteristics

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Baseline Measures

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel	Total
Overall Number of Participants	235	235	470

		1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel	Total
Age, Continuous Mean (Full Range) Unit of measure: years	Number Analyzed	235 participants	235 participants	470 participants
		50.9 (22 to 75)	50.6 (28 to 75)	50.75 (22 to 75)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	235 participants	235 participants	470 participants
	Female	235 100%	235 100%	470 100%
	Male	0 0%	0 0%	0 0%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Progression of Disease or Death
Measure Description	Progression Free Survival was defined as the time from the date of randomization to the day of documented disease progression or death due to any cause.
Time Frame	Event driven (after 350 events). Median observation time was approximately 16 months.

Analysis Population Description

Per protocol population included all participants who received at least one dose of study and who did not have any major protocol deviations.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	230	229
Time to Progression of Disease or Death Median (95% Confidence Interval) Unit of measure: Months	7.9 (6.9 to 8.5)	5.8 (4.9 to 7.1)

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Best Overall Response Being Complete Response (CR) or Partial Response (PR)
Measure Description	According to Response Evaluation Criteria in Solid Tumors (RECIST) criteria: CR is defined as the disappearance of all target lesions and PR is defined as at least a 30% decrease in the sum of the longest diameter (LD) of target lesions, taking as reference the nadir sum LD.
Time Frame	Until Progressive Disease (PD) or end of primary study treatment (up to 16 cycles) plus 28 days.

Analysis Population Description

Intent to treat population included all randomized participants.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	235	235
Percentage of Participants With Best Overall Response Being Complete Response (CR) or Partial Response (PR) Number (95% Confidence Interval) Unit of measure: Percentage of participants	45.1 (38.6 to 51.7)	37.4 (31.2 to 44.0)

3. Secondary Outcome Measure:

Measure Title	Time to Overall Response
Measure Description	For patients with Best Overall Response being Complete Response (CR) or Partial Response (PR), time to response was measured as the time from randomization to the first time when the measurement criteria for CR or PR were met. The percentage of participants with overall response within the given time ranges in each of the categories: Weeks 1-6, 7-12, 13-18, 19-24, 25-30, 31-36, and 43-48 are reported.

Time Frame	Until PD or end of primary study treatment (up to 16 cycles) plus 28 days.

Analysis Population Description

Intent to treat population included all randomized participants.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	235	235
Time to Overall Response Measure Type: Number Unit of measure: Percentage of participants		
Week 1-6	25	30
Week 7-12	48	30
Week 13-18	20	17
Week 19-24	7	7
Week 25-30	3	1
Week 31-36	3	2
Week 43-48	0	1

4. Secondary Outcome Measure:

Measure Title	Duration of Overall Response
Measure Description	Duration of overall response was measured from the time that measurement criteria were first met for Complete Response or Partial Response until the first date that progressive disease or death was documented.
Time Frame	Until PD or death. Median duration of response was approximately 7 months.

Analysis Population Description

Intent to treat population included all randomized participants.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	235	235
Duration of Overall Response Median (95% Confidence Interval) Unit of measure: Months	6.9 (6.1 to 8.6)	6.9 (5.8 to 9.0)

5. Secondary Outcome Measure:

Measure Title	Time to Treatment Failure
Measure Description	The time to treatment failure was the time from the date of randomization to the first occurrence of any of the following events: • adverse events • insufficient therapeutic response (disease progression) • death • failure to return • refusing treatment/being unwilling to cooperate • withdrawing consent.
Time Frame	Until premature withdrawal or end of primary study treatment (up to 16 cycles).

Analysis Population Description

Safety Population included all randomized participants who received study drug. Note: 14 patients randomized to 1250 mg/m^2 actual received an initial dose that ranged from 480 to 984 mg/m^2 so are included in the 825 mg/m^2 arm for safety.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	217	248
Time to Treatment Failure Median (95% Confidence Interval) Unit of measure: Months	5.1 (4.2 to 5.8)	4.6 (4.1 to 5.3)

6. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall Survival was measured as the time from the date of randomization to the date of death.
Time Frame	Throughout the study. Median observation time was approximately 16 months.

Analysis Population Description

Intent to treat population included all randomized participants.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	235	235

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Survival Median (95% Confidence Interval) Unit of measure: Months	16.4 (13.6 to 21.8)	15.1 (12.9 to 17.7)

7. Secondary Outcome Measure:

Measure Title	Number of Participants With Adverse Events and Serious Adverse Events
Measure Description	An adverse event was considered any unfavorable and unintended sign, symptom, or disease associated with the use of the study drug, whether or not considered related to the study drug. Preexisting conditions that worsened during the study were reported as adverse events. A serious adverse event is any experience that suggests a significant hazard, contraindication, side effect or precaution that: results in death, is Life-Threatening, required in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or is medically significant. Additional information about Adverse Events can be found in the Adverse Event Section.
Time Frame	First study drug intake until last study drug intake plus 28 days

Analysis Population Description

Safety Population included all randomized participants who received study drug. Note: 14 patients randomized to 1250 mg/m^2 actual received an initial dose that ranged from 480 to 984 mg/m^2 so are included in the 825 mg/m^2 arm for safety.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

Measured Values

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Overall Number of Participants Analyzed	217	248
Number of Participants With Adverse Events and Serious Adverse Events Measure Type: Number Unit of measure: Participants		

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
Adverse Events	206	234
Serious Adverse Events	41	53

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	Safety Population included all randomized participants who received study drug. Note: 14 patients randomized to the 1250 mg/m^2 arm actual received an initial dose that ranged from 480 to 984 mg/m^2 so were included in the 825 mg/m^2 arm for safety.

Reporting Groups

	Description
1250 mg/m^2 Capecitabine + Docetaxel	1250 mg/m^2 capecitabine (Xeloda®) orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel (Taxotere®) 75 mg/m^2 intravenous on day 1 of each 3 week cycle.
825 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 capecitabine orally twice a day on days 1 to 14 of each 3 week cycle, in combination with docetaxel 75 mg/m^2 intravenous on day 1 of each 3 week cycle.

All-Cause Mortality

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/

Serious Adverse Events

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Total	41/217 (18.89%)	53/248 (21.37%)
Blood and lymphatic system disorders		
Anaemia [A] †	0/217 (0%)	1/248 (0.4%)
Febrile neutropenia [A] †	13/217 (5.99%)	14/248 (5.65%)

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Leukopenia [A] †	2/217 (0.92%)	0/248 (0%)
Neutropenia [A] †	6/217 (2.76%)	4/248 (1.61%)
Cardiac disorders		
Atrial flutter [A] †	0/217 (0%)	1/248 (0.4%)
Cardiac failure [A] †	0/217 (0%)	1/248 (0.4%)
Cardiogenic shock [A] †	1/217 (0.46%)	0/248 (0%)
Cardiopulmonary failure [A] †	0/217 (0%)	1/248 (0.4%)
Gastrointestinal disorders		
Abdominal pain [A] †	1/217 (0.46%)	1/248 (0.4%)
Diarrhoea [A] †	2/217 (0.92%)	2/248 (0.81%)
Dyspepsia [A] †	0/217 (0%)	1/248 (0.4%)
Gastrointestinal ulcer haemorrhage [A] †	1/217 (0.46%)	0/248 (0%)
Ileus [A] †	0/217 (0%)	1/248 (0.4%)
Nausea [A] †	1/217 (0.46%)	0/248 (0%)
Stomatitis all [A] †	5/217 (2.3%)	0/248 (0%)
Vomiting [A] †	2/217 (0.92%)	2/248 (0.81%)
General disorders		
Asthenia [A] †	0/217 (0%)	3/248 (1.21%)
Disease progression [A] †	1/217 (0.46%)	2/248 (0.81%)
Injection site reaction [A] †	1/217 (0.46%)	0/248 (0%)
Non-cardiac chest pain [A] †	0/217 (0%)	1/248 (0.4%)
Pyrexia [A] †	1/217 (0.46%)	2/248 (0.81%)
Hepatobiliary disorders		

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Cholangitis acute [A] †	1/217 (0.46%)	0/248 (0%)
Cholecystitis [A] †	1/217 (0.46%)	0/248 (0%)
Hepatic failure [A] †	1/217 (0.46%)	1/248 (0.4%)
Infections and infestations		
Chest wall abscess [A] †	0/217 (0%)	1/248 (0.4%)
Gastroenteritis [A] †	0/217 (0%)	1/248 (0.4%)
Herpes zoster [A] †	0/217 (0%)	1/248 (0.4%)
Labyrinthitis [A] †	1/217 (0.46%)	0/248 (0%)
Nail infection [A] †	0/217 (0%)	1/248 (0.4%)
Neutropenic sepsis [A] †	0/217 (0%)	1/248 (0.4%)
Pneumonia [A] †	0/217 (0%)	1/248 (0.4%)
Sepsis [A] †	1/217 (0.46%)	0/248 (0%)
Viral infection [A] †	0/217 (0%)	1/248 (0.4%)
Injury, poisoning and procedural complications		
Brain herniation [A] †	0/217 (0%)	1/248 (0.4%)
Femoral neck fracture [A] †	0/217 (0%)	2/248 (0.81%)
Head injury [A] †	0/217 (0%)	1/248 (0.4%)
Thoracic vertebral fracture [A] †	0/217 (0%)	1/248 (0.4%)
Investigations		
Transaminases increased [A] †	0/217 (0%)	1/248 (0.4%)
Metabolism and nutrition disorders		
Diabetic ketoacidosis [A] †	1/217 (0.46%)	0/248 (0%)
Hyperglycaemia [A] †	0/217 (0%)	1/248 (0.4%)

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders		
Muscular weakness [A] †	0/217 (0%)	1/248 (0.4%)
Musculoskeletal pain [A] †	0/217 (0%)	1/248 (0.4%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer [A] †	1/217 (0.46%)	2/248 (0.81%)
Breast cancer metastatic [A] †	0/217 (0%)	1/248 (0.4%)
Malignant pleural effusion [A] †	0/217 (0%)	1/248 (0.4%)
Metastases to central nervous system [A] †	0/217 (0%)	1/248 (0.4%)
Nervous system disorders		
Neuropathy peripheral [A] †	0/217 (0%)	1/248 (0.4%)
Quadriparesis [A] †	0/217 (0%)	1/248 (0.4%)
Syncope [A] †	0/217 (0%)	1/248 (0.4%)
Psychiatric disorders		
Acute psychosis [A] †	1/217 (0.46%)	0/248 (0%)
Renal and urinary disorders		
Calculus urinary [A] †	1/217 (0.46%)	0/248 (0%)
Renal failure [A] †	0/217 (0%)	1/248 (0.4%)
Renal impairment [A] †	0/217 (0%)	1/248 (0.4%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome [A] †	1/217 (0.46%)	0/248 (0%)
Dyspnoea [A] †	1/217 (0.46%)	1/248 (0.4%)
Lung infiltration [A] †	0/217 (0%)	1/248 (0.4%)
Organising pneumonia [A] †	1/217 (0.46%)	0/248 (0%)

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Pleural effusion [A] †	0/217 (0%)	1/248 (0.4%)
Pleurisy [A] †	0/217 (0%)	1/248 (0.4%)
Pneumothorax [A] †	1/217 (0.46%)	0/248 (0%)
Pulmonary embolism [A] †	0/217 (0%)	3/248 (1.21%)
Respiratory distress [A] †	0/217 (0%)	1/248 (0.4%)
Respiratory failure [A] †	2/217 (0.92%)	1/248 (0.4%)
Skin and subcutaneous tissue disorders		
Palmar-Plantar erythrodysaesthesia syndrome [A] †	3/217 (1.38%)	1/248 (0.4%)
Vascular disorders		
Jugular vein thrombosis [A] †	0/217 (0%)	1/248 (0.4%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Total	192/217 (88.48%)	223/248 (89.92%)
Blood and lymphatic system disorders		
Anaemia [A] †	13/217 (5.99%)	15/248 (6.05%)
Leukopenia [A] †	21/217 (9.68%)	17/248 (6.85%)
Neutropenia [A] †	77/217 (35.48%)	70/248 (28.23%)
Gastrointestinal disorders		
Abdominal pain [A] †	14/217 (6.45%)	9/248 (3.63%)
Constipation [A] †	17/217 (7.83%)	17/248 (6.85%)

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Diarrhoea [A] †	73/217 (33.64%)	81/248 (32.66%)
Nausea [A] †	45/217 (20.74%)	58/248 (23.39%)
Stomatitis all [A] †	87/217 (40.09%)	88/248 (35.48%)
Vomiting [A] †	33/217 (15.21%)	45/248 (18.15%)
General disorders		
Asthenia [A] †	26/217 (11.98%)	34/248 (13.71%)
Fatigue [A] †	58/217 (26.73%)	50/248 (20.16%)
Oedema peripheral [A] †	18/217 (8.29%)	26/248 (10.48%)
Pyrexia [A] †	35/217 (16.13%)	27/248 (10.89%)
Hepatobiliary disorders		
Hyperbilirubinaemia [A] †	13/217 (5.99%)	10/248 (4.03%)
Investigations		
Aspartate aminotransferase increased [A] †	11/217 (5.07%)	7/248 (2.82%)
Blood bilirubin increased [A] †	18/217 (8.29%)	15/248 (6.05%)
Metabolism and nutrition disorders		
Decreased appetite [A] †	30/217 (13.82%)	36/248 (14.52%)
Musculoskeletal and connective tissue disorders		
Myalgia [A] †	15/217 (6.91%)	31/248 (12.5%)
Nervous system disorders		
Headache [A] †	14/217 (6.45%)	12/248 (4.84%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	16/217 (7.37%)	22/248 (8.87%)
Dyspnoea [A] †	12/217 (5.53%)	19/248 (7.66%)

	1250 mg/m^2 Capecitabine + Docetaxel	825 mg/m^2 Capecitabine + Docetaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Oropharyngeal pain [A] †	8/217 (3.69%)	14/248 (5.65%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	74/217 (34.1%)	82/248 (33.06%)
Nail disorder [A] †	26/217 (11.98%)	38/248 (15.32%)
Palmar−Plantar erythrodysaesthesia syndrome [A] †	102/217 (47%)	104/248 (41.94%)
Rash [A] †	14/217 (6.45%)	13/248 (5.24%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

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