ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/23/2016

ClinicalTrials.gov ID: NCT00454636

Study Identification

Unique Protocol ID:	ML20777
Brief Title:	A Study of Xeloda (Capecitabine) in Combination With Chemotherapy in Patients With Advanced and/or Metastatic Gastric Cancer.
Official Title:	Open Label, Phase II Study of Capecitabine (Xeloda®) as Fluoropyrimidine of Choice in Combination With Chemotherapy in Patients With Advanced and/or Metastatic Gastric Cancer Suitable for Treatment With a Fluoropyrimidine-Based Regimen
Secondary IDs:	

Study Status

Record Verification:	August 2016
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	July 2010 [Actual]
Study Completion:	July 2010 [Actual]

Sponsor/Collaborators

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

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: unknown Board Name: Ethics Committee from Hospital General Yague Board Affiliation: Unknown Phone: 947 28 18 00 Email: mjcoma@hgy.es
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Spain: Comité Ético de Investigación Clínica

Study Description

Brief Summary:	This study will assess the safety and efficacy of Xeloda, given in combination with standard chemotherapy regimens, for the first-line treatment of advanced and/or metastatic gastric cancer. All patients will receive Xeloda in combination with one of 4 standard chemotherapy regimens; the dose of Xeloda will be from 625mg/m2 - 1000mg/m2 bid orally, depending on the chemotherapy regimen used. The anticipated time on study treatment is until disease progression, and the target sample size is 100-500 individuals.
Detailed Description:	

Conditions

Conditions:	Gastric Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 158 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Cisplatin / Capecitabine Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, oral, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.	Drug: Cisplatin 80 mg/m2/day, intravenous (IV), every 3 weeks Drug: Capecitabine 1,000 mg/m2, oral, twice daily for 2 weeks, followed by 1 week of rest in each cycle Other Names: • Xeloda
Experimental: Epirubicin / Cisplatin / Capecitabine Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks.	Drug: Epirubicin 50 mg/m2/day, IV, every 3 weeks Drug: Cisplatin 60 mg/m2/day, IV, every 3 weeks Drug: Capecitabine 625 mg/m2, oral, twice daily per 3-week cycle Other Names: • Xeloda
Experimental: Epirubicin / Oxaliplatin / Capecitabine Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks.	Drug: Epirubicin 50 mg/m2/day, IV, every 3 weeks Drug: Capecitabine 625 mg/m2, oral, twice daily per 3-week cycle Other Names: • Xeloda Drug: Oxaliplatin 130 mg/m2/day, IV, every 3 weeks
Experimental: Docetaxel / Cisplatin / Capecitabine Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.	Drug: Cisplatin 60 mg/m2/day, IV, every 3 weeks Drug: Docetaxel 60 mg/m2/day, IV, every 3 weeks Drug: Capecitabine 825 mg/m2, oral, twice daily for 2 weeks Other Names: • Xeloda

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- adult patients, >=18 years of age;
- advanced or metastatic gastric cancer;
- Eastern Cooperative Oncology Group (ECOG) <=2.

Exclusion Criteria:

- previous chemotherapy (except adjuvant or neoadjuvant treatment >=6 months prior to study);
- evidence of central nervous system (CNS) metastasis;
- history of another malignancy within the last 5 years (except for successfully treated basal cell cancer of skin, or in situ cancer of the cervix);
- clinically significant cardiac disease.

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Spain

Alcoy, Alicante, Spain, 03804

Gijon, Asturias, Spain, 33394

Avila, Avila, Spain, 05071

Barcelona, Barcelona, Spain, 08916

Burgos, Burgos, Spain, 09006

Cádiz, Cadiz, Spain, 11009

Jerez de La Frontera, Cadiz, Spain, 11407

Puerto Real, Cadiz, Spain, 11510

Castellon, Castellon, Spain, 12002

Cordoba, Cordoba, Spain, 14004

Girona, Girona, Spain, 17007

Granada, Granada, Spain, 18014

Granada, Granada, Spain, 18003

Guadalajara, Guadalajara, Spain, 19002

San Sebastian, Guipuzcoa, Spain, 20080

Barbastro, Huesca, Spain, 22300

Huesca, Huesca, Spain, 22004

Palma De Mallorca, Islas Baleares, Spain, 07014

Palma de Mallorca, Islas Baleares, Spain, 07198

Jaen, Jaen, Spain, 23007

Ferrol, La Coruña, Spain, 15405

La Coruña, La Coruña, Spain, 15009

La Coruña, La Coruña, Spain, 15006

Santiago de Compostela, La Coruña, Spain, 15706

Logroño, La Rioja, Spain, 26006

Leon, Leon, Spain, 24071

Lerida, Lerida, Spain, 25198

Lugo, Lugo, Spain, 27004

Alcorcon, Madrid, Spain, 28922

Madrid, Madrid, Spain, 28041

Madrid, Madrid, Spain, 28222

Madrid, Madrid, Spain, 28034

Madrid, Madrid, Spain, 28033

Madrid, Madrid, Spain, 28034

Madrid, Madrid, Spain, 28935

Madrid, Madrid, Spain, 28223

Madrid, Madrid, Spain, 28050

Murcia, Murcia, Spain, 30008

Navarra, Navarra, Spain, 31008

Pamplona, Navarra, Spain, 31008

Orense, Orense, Spain, 32005

Palencia, Palencia, Spain, 34005

Pontevedra, Pontevedra, Spain, 36002

Vigo, Pontevedra, Spain, 36312

Salamanca, Salamanca, Spain, 37007

Sevilla, Sevilla, Spain, 41013

La Laguna, Tenerife, Spain, 38320

Toledo, Toledo, Spain, 45004

Valencia, Valencia, Spain, 41014

Valencia, Valencia, Spain, 46026

Bilbao, Vizcaya, Spain, 48013

Zaragoza, Zaragoza, Spain, 50009

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Overall Study

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Started	41	32	27	58
Completed	10	9	7	26
Not Completed	31	23	20	32
Adverse Event	10	6	9	15
Disease Progression	11	12	4	11
Protocol Violation	3	2	3	3

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Death	6	1	1	1
Patient refusal	1	1	3	2
Lost to Follow-up	0	1	0	0

Baseline Characteristics

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Baseline Measures

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine	Total
Number of Participants	41	32	27	58	158
Age, Continuous [units: years] Median (Full Range)	66 (39 to 77)	60 (38 to 78)	62 (40 to 79)	58 (20 to 78)	61 (20 to 79)
Gender, Male/Female [units: participants]					
Female	18	9	4	15	46
Male	23	23	23	43	112

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Grade 3 Hand-Foot Syndrome (HFS)
Measure Description	
Time Frame	Approximately 3.25 years
Safety Issue?	No

Analysis Population Description

Safety population: All participants who received at least one dose of study medication.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
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Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	41	32	27	58
Percentage of Participants With Grade 3 Hand-Foot Syndrome (HFS) [units: percentage of participants]	2.4	6.3	3.7	5.2

2. Secondary Outcome Measure:

Measure Title	Overall Response Rate (ORR)

Measure Description	ORR was defined as the percentage of participants achieving either a complete response (CR) or a partial response (PR), based on Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 criteria. CR was defined as the disappearance of all target lesions; for non-target lesions, disappearance of lesions and normal tumor marker levels. PR was defined as at least a 30% decrease in the sum of the longest diameter (LD) of target lesions, using the baseline sum LD as reference.
Time Frame	Approximately 3.25 years
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) population: included all participants who received at least one dose of study medication and had baseline and at least one subsequent tumor assessment.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	30	27	23	52
Overall Response Rate (ORR) [units: percentage of participants] Number (95% Confidence Interval)	43.3 (25.5 to 62.6)	40.7 (22.4 to 61.2)	69.6 (47.1 to 86.8)	59.6 (45.1 to 73.0)

3. Secondary Outcome Measure:

Measure Title	Progression-Free Survival (PFS)

Measure Description	PFS was defined as the time from the start of treatment to the first documentation of disease progression or death for any cause. Disease progression was based on Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 criteria and was defined as at least a 20% increase in the sum of LD of target lesions, taking as reference the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.
Time Frame	Approximately 3.25 years
Safety Issue?	No

Analysis Population Description

Safety population: All participants who received at least one dose of study medication.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	41	32	27	58
Progression-Free Survival (PFS) [units: months] Median (95% Confidence Interval)	4.43 (3.10 to 7.70)	5.17 (2.97 to 6.23)	7.07 (3.03 to 11.23)	7.87 (5.53 to 9.80)

4. Secondary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	OS was defined as the time elapsing from the date of the start of treatment until death, or last known follow-up.
Time Frame	Approximately 3.25 years

Safety Issue?	No

Analysis Population Description

Safety population: All participants who received at least one dose of study medication.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	41	32	27	58
Overall Survival (OS) [units: months] Median (95% Confidence Interval)	10.23 (4.73 to 12.60)	8.87 (5.30 to 14.57)	13.87 (5.37 to 24.07)	12.43 (10.60 to 15.67)

5. Secondary Outcome Measure:

Measure Title	Duration of Response
Measure Description	Duration of Response was defined as the time of complete response (CR) or partial response (PR) until the first date of recurrent or progressive disease, based on Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 criteria. CR was defined as the disappearance of all target lesions; for non-target lesions, disappearance of lesions and normal tumor marker levels. PR was defined as at least a 30% decrease in the sum of the longest diameter (LD) of target lesions, using the baseline sum LD as reference. Progressive disease was defined as at least a 20% increase in the sum of LD of target lesions, taking as reference the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.
Time Frame	Approximately 3.25 years

Safety Issue?	No

Analysis Population Description

Safety population: All participants who received at least one dose of study medication. Only participants who reported either a complete response or a partial response were assessed.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	13	11	16	31
Duration of Response [units: days] Mean (Standard Deviation)	308.92 (348.44)	154.09 (167.83)	203.06 (232.54)	205.52 (228.44)

6. Secondary Outcome Measure:

Measure Title	Time to Response
Measure Description	Time to Response was defined as the date of start of treatment until the first date of complete response (CR) or a partial response (PR), based on Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 criteria. CR was defined as the disappearance of all target lesions; for non-target lesions, disappearance of lesions and normal tumor marker levels. PR was defined as at least a 30% decrease in the sum of the longest diameter (LD) of target lesions, using the baseline sum LD as reference.
Time Frame	Approximately 3.25 years

Safety Issue?	No

Analysis Population Description

Safety population: All participants who received at least one dose of study medication. Only participants who reported either a complete response or a partial response were assessed.

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Measured Values

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
Number of Participants Analyzed	13	11	16	31
Time to Response [units: days] Mean (Standard Deviation)	132.92 (52.24)	126.64 (74.69)	123.50 (60.22)	138.16 (44.29)

Reported Adverse Events

Time Frame	Approximately 3.25 years
Additional Description	[Not specified]

Reporting Groups

	Description
Cisplatin / Capecitabine	Cisplatin, 80 mg/m2/day, intravenous (IV), every 3 weeks; capecitabine, 1,000 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Cisplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2, orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Epirubicin / Oxaliplatin / Capecitabine	Epirubicin, 50 mg/m2/day, IV, every 3 weeks; oxaliplatin, 130 mg/m2/day, IV, every 3 weeks; capecitabine, 625mg/m2 orally, twice daily per 3-week cycle. Study drugs were administered for at least 24 weeks
Docetaxel / Cisplatin / Capecitabine	Docetaxel, 60 mg/m2/day, IV, every 3 weeks; cisplatin, 60 mg/m2/day, IV, every 3 weeks; capecitabine, 825 mg/m2, orally, twice daily for 2 weeks, followed by 1 week of rest in each cycle. Study drugs were administered for at least 24 weeks.

Serious Adverse Events

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/41 (21.95%)	12/32 (37.5%)	12/27 (44.44%)	23/58 (39.66%)
Blood and lymphatic system disorders				
Anaemia [A] †	1/41 (2.44%)	0/32 (0%)	1/27 (3.7%)	1/58 (1.72%)
Febrile neutropenia [A] †	1/41 (2.44%)	4/32 (12.5%)	2/27 (7.41%)	4/58 (6.9%)
Neutropenia [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	3/58 (5.17%)
Thrombocytopenia [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Cardiac disorders				
Acute myocardial infarction [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Bradycardia [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Cardio-respiratory arrest [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Gastrointestinal disorders				
Abdominal pain [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Abdominal pain upper [A] †	1/41 (2.44%)	1/32 (3.12%)	0/27 (0%)	0/58 (0%)
Diarrhoea [A] †	1/41 (2.44%)	2/32 (6.25%)	1/27 (3.7%)	1/58 (1.72%)

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Enteritis [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Gastrointestinal haemorrhage [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Haematemesis [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Intestinal obstruction [A] †	0/41 (0%)	1/32 (3.12%)	2/27 (7.41%)	3/58 (5.17%)
Nausea [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	2/58 (3.45%)
Odynophagia [A] †	0/41 (0%)	1/32 (3.12%)	0/27 (0%)	0/58 (0%)
Stomatitis [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Vomiting [A] †	1/41 (2.44%)	1/32 (3.12%)	1/27 (3.7%)	5/58 (8.62%)
General disorders				
Asthenia [A] †	1/41 (2.44%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Chest pain [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
General physical health deterioration [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Pyrexia [A] †	0/41 (0%)	1/32 (3.12%)	1/27 (3.7%)	0/58 (0%)
Infections and infestations				
Anal abscess [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Bacteraemia gastroenteritis [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Clostridium [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Pneumonia [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Injury, poisoning and procedural complications				
Spinal fracture [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Investigations				
Aspartate aminotransferase increased [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Metabolism and nutrition disorders				
Hyperglycaemia [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Nervous system disorders				
Cerebellar infarction [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Cerebral haemorrhage [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Cerebral infarction [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Cerebral ischaemia [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Cerebrovascular accident [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Dizziness [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Dysarthria [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Hemiparesis [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Paraplegia [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Syncope [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Renal and urinary disorders				
Renal failure [A] †	0/41 (0%)	1/32 (3.12%)	0/27 (0%)	0/58 (0%)
Respiratory, thoracic and mediastinal disorders				
Dyspnoea [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Haemoptysis [A] †	1/41 (2.44%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Respiratory failure [A] †	0/41 (0%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Skin and subcutaneous tissue disorders				
Palmar-plantar erythrodysaesthesia syndrome [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	0/58 (0%)
Surgical and medical procedures				

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Limb operation [A] †	0/41 (0%)	1/32 (3.12%)	0/27 (0%)	0/58 (0%)
Vascular disorders				
Arterial thrombosis limb [A] †	0/41 (0%)	1/32 (3.12%)	0/27 (0%)	0/58 (0%)
Deep vein thrombosis [A] †	2/41 (4.88%)	0/32 (0%)	0/27 (0%)	0/58 (0%)
Peripheral ischaemia [A] †	1/41 (2.44%)	2/32 (6.25%)	0/27 (0%)	0/58 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 8.1

Other Adverse Events

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

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	39/41 (95.12%)	30/32 (93.75%)	27/27 (100%)	54/58 (93.1%)
Blood and lymphatic system disorders				
Anaemia [A] †	10/41 (24.39%)	12/32 (37.5%)	7/27 (25.93%)	19/58 (32.76%)
Febrile neutropenia [A] †	0/41 (0%)	1/32 (3.12%)	2/27 (7.41%)	2/58 (3.45%)
Leukopenia [A] †	1/41 (2.44%)	2/32 (6.25%)	4/27 (14.81%)	4/58 (6.9%)
Neutropenia [A] †	18/41 (43.9%)	10/32 (31.25%)	13/27 (48.15%)	8/58 (13.79%)
Thrombocytopenia [A] †	8/41 (19.51%)	1/32 (3.12%)	6/27 (22.22%)	3/58 (5.17%)
Gastrointestinal disorders				
Abdominal pain [A] †	5/41 (12.2%)	5/32 (15.62%)	4/27 (14.81%)	4/58 (6.9%)
Abdominal pain upper [A] †	5/41 (12.2%)	3/32 (9.38%)	2/27 (7.41%)	6/58 (10.34%)
Constipation [A] †	3/41 (7.32%)	9/32 (28.12%)	6/27 (22.22%)	13/58 (22.41%)
Diarrhoea [A] †	12/41 (29.27%)	8/32 (25%)	13/27 (48.15%)	28/58 (48.28%)

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Dry mouth [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	4/58 (6.9%)
Dyspepsia [A] †	0/41 (0%)	3/32 (9.38%)	0/27 (0%)	7/58 (12.07%)
Dysphagia [A] †	0/41 (0%)	0/32 (0%)	2/27 (7.41%)	1/58 (1.72%)
Nausea [A] †	10/41 (24.39%)	15/32 (46.88%)	10/27 (37.04%)	17/58 (29.31%)
Vomiting [A] †	16/41 (39.02%)	17/32 (53.12%)	15/27 (55.56%)	24/58 (41.38%)
General disorders				
Asthenia [A] †	20/41 (48.78%)	14/32 (43.75%)	17/27 (62.96%)	36/58 (62.07%)
Mucosal inflammation [A] †	7/41 (17.07%)	9/32 (28.12%)	4/27 (14.81%)	11/58 (18.97%)
Oedema [A] †	1/41 (2.44%)	0/32 (0%)	2/27 (7.41%)	2/58 (3.45%)
Oedema peripheral [A] †	1/41 (2.44%)	3/32 (9.38%)	2/27 (7.41%)	1/58 (1.72%)
Pain [A] †	2/41 (4.88%)	0/32 (0%)	1/27 (3.7%)	3/58 (5.17%)
Pyrexia [A] †	3/41 (7.32%)	6/32 (18.75%)	3/27 (11.11%)	9/58 (15.52%)
Infections and infestations				
Nasopharyngitis [A] †	0/41 (0%)	2/32 (6.25%)	1/27 (3.7%)	3/58 (5.17%)
Oral candidiasis [A] †	0/41 (0%)	0/32 (0%)	2/27 (7.41%)	0/58 (0%)
Pneumonia [A] †	0/41 (0%)	1/32 (3.12%)	2/27 (7.41%)	2/58 (3.45%)
Respiratory tract infection [A] †	1/41 (2.44%)	0/32 (0%)	1/27 (3.7%)	3/58 (5.17%)
Urinary tract infection [A] †	1/41 (2.44%)	1/32 (3.12%)	1/27 (3.7%)	3/58 (5.17%)
Investigations				
Weight decreased [A] †	1/41 (2.44%)	2/32 (6.25%)	0/27 (0%)	0/58 (0%)
Metabolism and nutrition disorders				
Decreased appetite [A] †	6/41 (14.63%)	9/32 (28.12%)	8/27 (29.63%)	15/58 (25.86%)

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hyperglycaemia [A] †	1/41 (2.44%)	2/32 (6.25%)	1/27 (3.7%)	0/58 (0%)
Hypokalaemia [A] †	3/41 (7.32%)	1/32 (3.12%)	2/27 (7.41%)	2/58 (3.45%)
Musculoskeletal and connective tissue disorders				
Back pain [A] †	2/41 (4.88%)	2/32 (6.25%)	2/27 (7.41%)	4/58 (6.9%)
Nervous system disorders				
Dizziness [A] †	3/41 (7.32%)	0/32 (0%)	5/27 (18.52%)	1/58 (1.72%)
Dysaesthesia [A] †	1/41 (2.44%)	0/32 (0%)	5/27 (18.52%)	0/58 (0%)
Dysgeusia [A] †	0/41 (0%)	1/32 (3.12%)	2/27 (7.41%)	3/58 (5.17%)
Neurotoxicity [A] †	0/41 (0%)	1/32 (3.12%)	3/27 (11.11%)	7/58 (12.07%)
Paraesthesia [A] †	1/41 (2.44%)	0/32 (0%)	6/27 (22.22%)	8/58 (13.79%)
Psychiatric disorders				
Insomnia [A] †	1/41 (2.44%)	0/32 (0%)	1/27 (3.7%)	3/58 (5.17%)
Renal and urinary disorders				
Renal failure [A] †	3/41 (7.32%)	0/32 (0%)	0/27 (0%)	1/58 (1.72%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	1/41 (2.44%)	0/32 (0%)	1/27 (3.7%)	3/58 (5.17%)
Dyspnoea [A] †	1/41 (2.44%)	2/32 (6.25%)	2/27 (7.41%)	2/58 (3.45%)
Hiccups [A] †	0/41 (0%)	1/32 (3.12%)	1/27 (3.7%)	3/58 (5.17%)
Skin and subcutaneous tissue disorders				
Alopecia [A] †	0/41 (0%)	15/32 (46.88%)	5/27 (18.52%)	14/58 (24.14%)
Erythema [A] †	0/41 (0%)	0/32 (0%)	1/27 (3.7%)	4/58 (6.9%)
Onycholysis [A] †	0/41 (0%)	2/32 (6.25%)	0/27 (0%)	2/58 (3.45%)

	Cisplatin / Capecitabine	Epirubicin / Cisplatin / Capecitabine	Epirubicin / Oxaliplatin / Capecitabine	Docetaxel / Cisplatin / Capecitabine
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Palmar-plantar erythrodysaesthesia syndrome [A] †	6/41 (14.63%)	9/32 (28.12%)	4/27 (14.81%)	11/58 (18.97%)
Vascular disorders				
Deep vein thrombosis [A] †	1/41 (2.44%)	3/32 (9.38%)	0/27 (0%)	1/58 (1.72%)
Hypotension [A] †	0/41 (0%)	0/32 (0%)	2/27 (7.41%)	0/58 (0%)
Phlebitis [A] †	0/41 (0%)	2/32 (6.25%)	0/27 (0%)	2/58 (3.45%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 8.1

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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