ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 07/14/2016

ClinicalTrials.gov ID: NCT00796718

Study Identification

Unique Protocol ID:	ML21800
Brief Title:	A Study of Xeloda (Capecitabine) Plus Radiotherapy in Participants With Locally Advanced Rectal Cancer
Official Title:	An Open Label Study of the Effect of Xeloda and Radiotherapy on Pathological Response Rate in Patients With Locally Advanced Rectal Cancer
Secondary IDs:	2008-003980-38

Study Status

Record Verification:	July 2016
Overall Status:	Completed
Study Start:	October 2008
Primary Completion:	August 2010 [Actual]
Study Completion:	August 2010 [Actual]

Sponsor/Collaborators

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

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? No

	Delayed Posting?
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 08.07.08 Board Name: Ethics Committee of National Cancer Institute Board Affiliation: Unknown Phone: 421 259 378 740 Email: kristina.krizanova@nou.sk
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Slovakia: State Institute for Drug Control

Study Description

Brief Summary:	This single arm study will assess the efficacy and safety of treatment with Xeloda plus standard pelvic radiotherapy in participants with locally advanced rectal cancer. Eligible participants will receive Xeloda 825mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks, followed by surgery within 6 weeks after completion of treatment. The anticipated time on study treatment is < 3 months, and the target sample size is < 100 individuals.
Detailed Description:	

Conditions

Conditions:	Colorectal Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 62 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Capecitabine Capecitabine orally twice daily plus standard radiotherapy for 5 weeks, followed by surgery within 6 weeks after completion of treatment.	Radiation: Standard radiotherapy Administered as prescribed according to normal clinical practice. Drug: Capecitabine [Xeloda] 825 milligrams per meter square (mg/m^2) orally twice daily for 5 weeks. Other Names: • Xeloda®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 80 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- adult patients, 18-80 years of age;
- rectal cancer;
- planned surgery, and likely to benefit from pre-operative combined chemo-radiotherapy;
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2

Exclusion Criteria:

- previous radiotherapy or chemotherapy for colorectal cancer;
- clinically significant cardiovascular disease;
- significant gastric or small intestine disease;
- serious uncontrolled active infection

Contacts/Locations

Study Officials: Clinical Trials
Study Director

Hoffmann-La Roche

Locations: Slovakia
Bratislava, Slovakia, 833 10

Banska Bystrica, Slovakia, 975 17

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	A total of 62 participants were enrolled in the study.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 milligrams per meter square (mg/m^2) orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Overall Study

	Capecitabine
Started	62
Completed	53
Not Completed	9
Adverse Event	2
Exclusion Criteria	1
Lost to Follow-up	5

	Capecitabine
Withdrawal by Informed Consent	1

Baseline Characteristics

Analysis Population Description
All enrolled participants.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Baseline Measures

	Capecitabine
Number of Participants	62
Age, Continuous [units: years] Mean (Standard Deviation)	59.0 (9.4)
Gender, Male/Female [units: participants]	
Female	22
Male	40

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Pathological Complete Response
Measure Description	Pathological complete response was defined as the absence of viable tumor cells in the tumor specimen, including regional lymph nodes determined with standard histological procedures.
Time Frame	Up to 11 weeks (assessed at the time of post-treatment surgery)
Safety Issue?	No

Analysis Population Description
Participants with available data.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Measured Values

	Capecitabine
Number of Participants Analyzed	50
Percentage of Participants With Pathological Complete Response [units: percentage of participants]	16

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Response to Treatment Assessed 4-6 Weeks After the Completion of Radiochemotherapy (Complete Response, Partial Remission or No Response to the Treatment)
Measure Description	Complete response was defined as the disappearance of all target and non-target lesions. Partial remission was defined as ≥ 30% decrease in the sum of the longest diameter (SLD) of target lesions, taking as reference the baseline SLD, or the persistence of 1 or more non-target lesions. No response to treatment was defined as neither sufficient shrinkage to qualify for partial remission nor sufficient increase to qualify for progressive disease, compared to the baseline SLD.
Time Frame	Up to 11 weeks (assessed 4-6 weeks after the completion of radiochemotherapy)
Safety Issue?	No

Analysis Population Description

Participants with available data.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Measured Values

	Capecitabine
Number of Participants Analyzed	49

	Capecitabine
Percentage of Participants With Response to Treatment Assessed 4-6 Weeks After the Completion of Radiochemotherapy (Complete Response, Partial Remission or No Response to the Treatment) [units: percentage of participants]	
Complete Response	2
Partial Remission	12.2
No Response	77.6

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Response to the Treatment Assessed 1 Month After Surgery (Complete Response, Partial Remission or No Response to the Treatment)
Measure Description	Complete response was defined as the disappearance of all target and non-target lesions. Partial remission was defined as ≥ 30% decrease in the sum of the longest diameter (SLD) of target lesions, taking as reference the baseline SLD, or the persistence of 1 or more non-target lesions. No response to treatment was defined as neither sufficient shrinkage to qualify for partial remission nor sufficient increase to qualify for progressive disease, compared to the baseline SLD.
Time Frame	Up to 15 weeks (assessed 1 month after surgery)
Safety Issue?	No

Analysis Population Description

Participants with available data.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Measured Values

	Capecitabine
Number of Participants Analyzed	50

	Capecitabine
Percentage of Participants With Response to the Treatment Assessed 1 Month After Surgery (Complete Response, Partial Remission or No Response to the Treatment) [units: percentage of participants]	
Complete Response	56
Partial Remission	10
No Response	14

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Adverse Events
Measure Description	An adverse event was defined as any untoward medical occurrence in a participant administered the investigational product which does not necessarily have a causal relationship with this treatment.
Time Frame	Up to 15 weeks
Safety Issue?	No

Analysis Population Description

All enrolled participants.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Measured Values

	Capecitabine
Number of Participants Analyzed	62
Percentage of Participants With Adverse Events [units: percentage of participants]	91.9

Reported Adverse Events

Time Frame	Up to 15 weeks
Additional Description	All enrolled participants.

Reporting Groups

	Description
Capecitabine	Capecitabine 825 mg/m^2 orally twice daily plus standard radiotherapy for 5 weeks as prescribed according to normal clinical practice, followed by surgery within 6 weeks after completion of treatment.

Serious Adverse Events

	Capecitabine
	Affected/At Risk (%)
Total	4/62 (6.45%)
Cardiac disorders	
Ventricular fibrillation [A] †	1/62 (1.61%)
Gastrointestinal disorders	
Diarrhea [A] †	2/62 (3.23%)
Hemorrhoidal inflammation [A] †	1/62 (1.61%)
Ileus [A] †	1/62 (1.61%)
Infections and infestations	
Sepsis [A] †	1/62 (1.61%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (19.0)

Other Adverse Events

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

	Capecitabine
	Affected/At Risk (%)
Total	49/62 (79.03%)
Blood and lymphatic system disorders	

	Capecitabine
	Affected/At Risk (%)
Anemia [A] †	4/62 (6.45%)
Leukopenia [A] †	8/62 (12.9%)
Neutropenia [A] †	5/62 (8.06%)
Gastrointestinal disorders	
Abdominal pain [A] †	8/62 (12.9%)
Diarrhea [A] †	21/62 (33.87%)
Nausea [A] †	7/62 (11.29%)
Rectal pain [A] †	12/62 (19.35%)
General disorders	
Fatigue [A] †	6/62 (9.68%)
Infections and infestations	
Upper respiratory infection [A] †	4/62 (6.45%)
Injury, poisoning and procedural complications	
Dermatitis radiation [A] †	20/62 (32.26%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Cyst in the liver [A] †	4/62 (6.45%)
Skin and subcutaneous tissue disorders	
Erythema [A] †	4/62 (6.45%)
Palmar-plantar erythrodysesthesia syndrome [A] †	4/62 (6.45%)
Vascular disorders	
Hypertension [A] †	4/62 (6.45%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (19.0)

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.

Results Point of Contact:

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