ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 09/26/2016

ClinicalTrials.gov ID: NCT00977379

Study Identification

Unique Protocol ID:	ML21873
Brief Title:	A Study of Whole Brain Radiation Therapy and Capecitabine in Breast Cancer Participants With Newly Diagnosed Brain Metastasis (XERAD)
Official Title:	XERAD: Open-Label, Phase II, Randomized, Comparative, Multicentre Trial of Concurrent Whole Brain Radiation Therapy (WBRT) and Capecitabine (Xeloda®) Followed by Maintenance Capecitabine Compared With Standard WBRT in Breast Cancer Patients With Newly Diagnosed Brain Metastasis
Secondary IDs:	2008-007349-30

Study Status

Record Verification:	September 2016
Overall Status:	Terminated [Due to an insufficient number of participants enrolled.]
Study Start:	August 2009
Primary Completion:	February 2011 [Actual]
Study Completion:	February 2011 [Actual]

Sponsor/Collaborators

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

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 11-09 Board Name: Comité de Protection des Personnes Ile-de-France VI Board Affiliation: Comité de Protection des Personnes Ile-de-France VI Phone: +33 142161683 Email: cppidf6.salpetriere@yahoo.com
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Study Description

Brief Summary:	This open-label, randomized, parallel arm study will evaluate the effect of capecitabine administered concurrently with WBRT and as maintenance therapy in participants with breast cancer and newly diagnosed brain metastases. Participants will be randomized to receive either capecitabine with 10 days standard WBRT, or WBRT alone. Maintenance therapy will follow with capecitabine or another systemic therapy in the WBRT only group.
Detailed Description:	

Conditions

Conditions:	Breast Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment

Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	24 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: WBRT Followed by Standard of Care Participants will receive 3000 centi-Gray (cGy) WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants will be followed during the treatment until the halting of standard of care for any reason (central nervous system [CNS] or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).	Radiation: WBRT 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction). Drug: Standard of Care The choice of standard of care will be at the discretion of the treating oncologist. The protocol does not specify any particular standard of care treatment.
Experimental: WBRT+Capecitabine Followed by Capecitabine Maintenance Participants will receive 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 milligrams per square meter (mg/m^2) orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).	Radiation: WBRT 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction). Drug: Capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2. Other Names: • Xeloda

Outcome Measures

[See Results Section.]

Eligibility

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

Criteria: Inclusion Criteria:

- Women with histologically confirmed breast cancer with known human epidermal receptor-2 (HER2) and hormone status
- Newly diagnosed CNS metastasis with at least one brain lesion measuring greater than or equal to (>/=) 1 centimeter (cm) or two lesions measuring >/= 0.5 to less than (<) 1 cm in longest dimension
- Participant not eligible for or refusing surgery or stereotactic radiosurgery
- Eastern cooperative oncology group (EOCG) performance status 0 to 2

Exclusion Criteria:

- Prior treatment of brain metastases
- Leptomeningeal disease
- Known contra-indication to radiotherapy or magnetic resonance imaging (MRI) or capecitabine

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: France
Bobigny, France, 93009

Paris, France, 75475

Dijon, France, 21079

Rouen, France, 76000

Beziers, France, 34500

Paris, France, 75651

Lille, France, 59020

Nantes, France, 44202

Lyon, France, 69373

Le Mans, France, 72015

Salouel, France, 80480

Narbonne, France, 11780

Montpellier, France, 34928

Arras, France, 62000

Nice, France, 06000

Beuvry, France, 62660

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 centi-Gray (cGy) whole brain radiation therapy (WBRT) in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (central nervous system [CNS] or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 milligrams per square meter (mg/m^2) orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Overall Study

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Started	12 [1]	12 [1]
Treated	12	11

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Completed	0	0
Not Completed	12	12
Withdrawal by Subject	1	1
Death	7	9
Premature Study Termination	4	0
Participant Moving House	0	1
Randomization Error	0	1

[1] Randomized

Baseline Characteristics

Analysis Population Description

Intent to treat (ITT) population included all randomized participants except one participant from “WBRT+Capecitabine Followed by Capecitabine Maintenance” arm who was randomized by error.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Baseline Measures

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance	Total
Number of Participants	12	11	23

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance	Total
Age, Continuous [units: years] Mean (Standard Deviation)	54.8 (15.6)	57.8 (13.1)	56.2 (14.2)
Gender, Male/Female [units: participants]			
Female	12	11	23
Male	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Best Objective Central Nervous System (CNS) Response, Assessed by Centralized Independent Expert According to Magnetic Resonance Imaging (MRI) - Intent-to-Treat (ITT) Population
Measure Description	Best objective CNS response was defined as having complete response (CR) or partial response (PR) for CNS metastasis, assessed by contrast-enhanced MRI using response evaluation criteria in solid tumors (RECIST). CR: disappearance of all CNS lesions. PR: greater than or equal to (>/=) 30 percent (%) decrease in sum of longest diameters (LD) of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until disease progression (PD), unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).

	Description
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Best Objective Central Nervous System (CNS) Response, Assessed by Centralized Independent Expert According to Magnetic Resonance Imaging (MRI) - Intent-to-Treat (ITT) Population [units: percentage of participants]	25.0	36.4

2. Primary Outcome Measure:

Measure Title	Percentage of Participants With Best Objective CNS Response, Assessed by Centralized Independent Expert According to MRI - Per-Protocol (PP) Population
Measure Description	Best objective CNS response was defined as having CR or PR for CNS metastasis, assessed by contrast-enhanced MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30% decrease in sum of LD of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

PP population included all ITT population participants excluding participants with following major protocol violations: inclusion and exclusion criteria not met; intake of prohibited treatment, protocol design and/or visit dates not respected; and missing values for main criterion without premature withdrawal.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	10	9
Percentage of Participants With Best Objective CNS Response, Assessed by Centralized Independent Expert According to MRI - Per-Protocol (PP) Population [units: percentage of participants]	20.0	33.3

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective CNS Response at 4 Weeks After Completion of WBRT, Assessed by Centralized Independent Expert According to MRI
Measure Description	Objective CNS response was defined as having CR or PR for CNS metastasis, assessed by contrast-enhanced MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30% decrease in sum of LD of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first up to 4 weeks after completion of WBRT (up to approximately 7 weeks)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Objective CNS Response at 4 Weeks After Completion of WBRT, Assessed by Centralized Independent Expert According to MRI [units: percentage of participants]	25.0	36.4

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Best Objective CNS Response, Assessed by Investigator According to MRI
Measure Description	Best objective CNS response was defined as having CR or PR for CNS metastasis, assessed by contrast-enhanced MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30% decrease in sum of LD of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Best Objective CNS Response, Assessed by Investigator According to MRI [units: percentage of participants]	50.0	54.5

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective CNS Response at 4 Weeks After Completion of WBRT, Assessed by Centralized Independent Expert According to MRI in 3 Dimension
Measure Description	Objective CNS response was defined as having CR or PR for CNS metastasis, assessed by 3 dimensional MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30% decrease in sum of LD of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first up to 4 weeks after completion of WBRT (up to approximately 7 weeks)
Safety Issue?	No

Analysis Population Description

The data for this outcome was not collected as per changes in planned analysis because sufficient information on the method used was not available.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Clinical Benefit, Assessed by Investigator According to MRI
Measure Description	Clinical benefit was defined as having CR, PR, or stable disease (SD), assessed by contrast-enhanced MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30 % decrease in sum of LD of CNS lesions taking as reference the baseline sum LD. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD) taking as reference smallest sum LD since treatment started. PD: a 20% or greater increase in the sum of the LD of CNS lesions taking as reference the smallest sum LD recorded since the treatment started or appearance of one or more CNS lesions and/or unequivocal progression of existing CNS lesions.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Clinical Benefit, Assessed by Investigator According to MRI [units: percentage of participants]	83.3	72.7

7. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective CNS Response at 4 Weeks After Completion of WBRT, Assessed by Investigator According to MRI
Measure Description	Objective CNS response was defined as having CR or PR for CNS metastasis, assessed by contrast-enhanced MRI using RECIST. CR: disappearance of all CNS lesions. PR: >/=30 % decrease in sum of LD of CNS lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first up to 4 weeks after completion of WBRT (up to approximately 7 weeks)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Objective CNS Response at 4 Weeks After Completion of WBRT, Assessed by Investigator According to MRI [units: percentage of participants]	41.7	27.3

8. Secondary Outcome Measure:

Measure Title	Duration of CNS Response, Assessed by Investigator According to MRI
Measure Description	Duration of CNS response was defined as the time from first documented cranial CR or PR (whichever was recorded first) until the first date CNS recurrence or progression was documented as assessed by contrast-enhanced MRI according to RECIST criteria but without exam for response confirmation. CR: disappearance of all CNS lesions. PR: >/ =30 % decrease in sum of LD of CNS lesions taking as reference the baseline sum LD. PD: a 20% or greater increase in the sum of the LD of CNS lesions taking as reference the smallest sum LD recorded since the treatment started or appearance of one or more CNS lesions and/or unequivocal progression of existing CNS lesions.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population. Here, number of participants analyzed = participants having had a CR or PR during the study.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	6	6
Duration of CNS Response, Assessed by Investigator According to MRI [units: months] Median (Full Range)	6.2 (0 to 16)	2.6 (0 to 11)

9. Secondary Outcome Measure:

Measure Title	Time to CNS Progression, Assessed by Investigator According to MRI
Measure Description	Time to CNS progression was defined as the time from start of study treatment to first documentation of PD or death due to CNS metastasis. PD was assessed by contrast-enhanced MRI according to RECIST. PD: a 20% or greater increase in the sum of the LD of CNS lesions taking as reference the smallest sum LD recorded since the treatment started or appearance of one or more CNS lesions and/or unequivocal progression of existing CNS lesions.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Time to CNS Progression, Assessed by Investigator According to MRI [units: months] Median (Full Range)	3.8 (1 to 17)	3.4 (1 to 15)

10. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Best Objective Extra-cranial Disease Response, Assessed by Investigator According to Computed Tomography (CT)
Measure Description	Best objective extra-cranial response was defined as having CR or PR for extra-cranial lesions, assessed by CT using RECIST. CR: disappearance of all extra-cranial lesions. PR: >/=30 % decrease in sum of LD of extra-cranial lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Best Objective Extra-cranial Disease Response, Assessed by Investigator According to Computed Tomography (CT) [units: percentage of participants]	0.0	9.1

11. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective Extra-cranial Disease Response at 4 Weeks After Completion of WBRT, Assessed by Investigator According to CT
Measure Description	Objective extra-cranial response was defined as having CR or PR for extra-cranial lesions, assessed by CT using RECIST. CR: disappearance of all extra-cranial lesions. PR: >/=30 % decrease in sum of LD of extra-cranial lesions taking as reference the baseline sum LD.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first up to 4 weeks after completion of WBRT (up to approximately 7 weeks)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Percentage of Participants With Objective Extra-cranial Disease Response at 4 Weeks After Completion of WBRT, Assessed by Investigator According to CT [units: percentage of participants]	0.0	9.1

12. Secondary Outcome Measure:

Measure Title	Time to Extra-cranial Disease Progression, Assessed by Investigator According to CT
Measure Description	Time to extra-cranial progression was defined as the time from start of study treatment to first documentation of PD or death due to extra-cranial lesions. PD was assessed by CT according to RECIST. PD: a 20% or greater increase in the sum of the LD of extra-cranial lesions taking as reference the smallest sum LD recorded since the treatment started or appearance of one or more extra-cranial lesions and/or unequivocal progression of existing extra-cranial lesions.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Time to Extra-cranial Disease Progression, Assessed by Investigator According to CT [units: months] Median (Full Range)	3.5 (1 to 10)	2.7 (1 to 15)

13. Secondary Outcome Measure:

Measure Title	Time to Progression, Assessed by Investigator According to MRI and CT
Measure Description	Time to progression was defined as the time from start of study treatment to first documentation of PD or death due to tumor (CNS or extra-cranial). PD was assessed by MRI or CT according to RECIST. PD: a 20% or greater increase in the sum of the LD of CNS or extra-cranial lesions taking as reference the smallest sum LD recorded since the treatment started or appearance of one or more CNS or extra-cranial lesions and/or unequivocal progression of existing CNS or extra-cranial lesions.
Time Frame	Baseline until PD, unacceptable toxicity, withdrawal of consent, change of therapeutic strategy (for arm "WBRT Followed by Standard of Care" only), or death, whichever occurred first (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Time to Progression, Assessed by Investigator According to MRI and CT [units: months] Median (Full Range)	3.3 (1 to 10)	2.7 (1 to 15)

14. Secondary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	OS was defined as the time from the start of study treatment to date of death due to any cause. OS was assessed using Kaplan-Meier analysis.
Time Frame	Baseline until death (up to approximately 1 year 5.5 months overall)
Safety Issue?	No

Analysis Population Description

ITT population.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	12	11
Overall Survival (OS) [units: months] Median (95% Confidence Interval)	9.8 (4.3 to 17.0)	4.6 (2.3 to 8.9)

15. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Mini Mental State (MMS) Total Score
Measure Description	MMS was an 11-question measure that tested five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. Four items were scored on a scale of 0 to 1; 1 item was scored on a scale of 0 to 2; 3 items were scored on a scale of 0 to 3; and 3 items were scored on a scale of 0 to 5. MMS total score was obtained by adding the scores of all individual items and ranged from 0 to 30, where higher scores indicate better cognitive state.
Time Frame	Baseline, Up to end of Treatment (up to 10.6 months overall)
Safety Issue?	No

Analysis Population Description

ITT population. Here, number of participants analyzed = participants evaluable for this outcome.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Measured Values

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
Number of Participants Analyzed	10	8
Absolute Change From Baseline in Mini Mental State (MMS) Total Score [units: units on a scale] Mean (Standard Deviation)	-1.5 (4.3)	0.9 (3.2)

Reported Adverse Events

Time Frame	Throughout study (up to approximately 1 year 5.5 months overall)
Additional Description	Safety population included all participants from “WBRT Followed by Standard of Care” arm who received at least one fraction of WBRT and all participants from “WBRT+Capecitabine Followed by Capecitabine Maintenance” arm who received at least one dose of capecitabine or one fraction of WBRT.

Reporting Groups

	Description
WBRT Followed by Standard of Care	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) followed by standard of care therapy at the discretion of the treating oncologist starting no earlier than 2 weeks after completion of WBRT. The participants were followed during the treatment until the halting of standard of care for any reason (CNS or extra-cranial tumor progression, unacceptable toxicity, change of therapeutic strategy, withdrawal of participant consent, or death).
WBRT+Capecitabine Followed by Capecitabine Maintenance	Participants received 3000 cGy WBRT in 10 single daily fractions over 12 to 14 days (300 cGy / fraction) concurrent with capecitabine 825 mg/m^2 orally twice daily, Days 1-14 of a 21 day cycle for 1 cycle followed by capecitabine 1000 mg/m^2 orally twice daily Days 1-14 every 21 days starting with Cycle 2, one week after completion of WBRT and continuing until the halting of capecitabine for any reason (CNS or extra-cranial progression, unacceptable toxicity, withdrawal of participant consent or death).

Serious Adverse Events

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/12 (50%)	6/11 (54.55%)
Gastrointestinal disorders		
Colitis [A] *	0/12 (0%)	1/11 (9.09%)
General disorders		
Asthenia [A] *	1/12 (8.33%)	0/11 (0%)
Chest pain [A] *	1/12 (8.33%)	0/11 (0%)
General physical health deterioration [A] *	1/12 (8.33%)	2/11 (18.18%)
Nervous system disorders		
Cerebrovascular accident [A] *	1/12 (8.33%)	0/11 (0%)
Depressed level of consciousness [A] *	0/12 (0%)	1/11 (9.09%)
Epilepsy [A] *	1/12 (8.33%)	1/11 (9.09%)
Intracranial pressure increased [A] *	0/12 (0%)	1/11 (9.09%)
Myoclonus [A] *	1/12 (8.33%)	0/11 (0%)
Syncope [A] *	0/12 (0%)	1/11 (9.09%)

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Psychiatric disorders		
Completed suicide [A] *	0/12 (0%)	1/11 (9.09%)
Respiratory, thoracic and mediastinal disorders		
Pleural effusion [A] *	1/12 (8.33%)	0/11 (0%)
Pulmonary embolism [A] *	0/12 (0%)	1/11 (9.09%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (13.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Total	11/12 (91.67%)	10/11 (90.91%)
Blood and lymphatic system disorders		
Anaemia [A] *	1/12 (8.33%)	0/11 (0%)
Leukopenia [A] *	3/12 (25%)	1/11 (9.09%)
Lymphopenia [A] *	1/12 (8.33%)	1/11 (9.09%)
Neutropenia [A] *	2/12 (16.67%)	1/11 (9.09%)
Thrombocytopenia [A] *	1/12 (8.33%)	1/11 (9.09%)
Eye disorders		
Eyelid Oedema [A] *	1/12 (8.33%)	0/11 (0%)
Papilloedema [A] *	1/12 (8.33%)	0/11 (0%)
Visual Acuity Reduced [A] *	2/12 (16.67%)	0/11 (0%)
Visual Impairment [A] *	1/12 (8.33%)	0/11 (0%)

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders		
Constipation [A] *	0/12 (0%)	1/11 (9.09%)
Diarrhoea [A] *	1/12 (8.33%)	3/11 (27.27%)
Dry Mouth [A] *	0/12 (0%)	1/11 (9.09%)
Dysphagia [A] *	1/12 (8.33%)	0/11 (0%)
Haemorrhoids [A] *	1/12 (8.33%)	0/11 (0%)
Nausea [A] *	4/12 (33.33%)	5/11 (45.45%)
Parotid Gland Enlargement [A] *	1/12 (8.33%)	0/11 (0%)
Stomatitis [A] *	1/12 (8.33%)	0/11 (0%)
Vomiting [A] *	1/12 (8.33%)	6/11 (54.55%)
General disorders		
Asthenia [A] *	6/12 (50%)	5/11 (45.45%)
Chest Pain [A] *	2/12 (16.67%)	1/11 (9.09%)
Facial Pain [A] *	1/12 (8.33%)	0/11 (0%)
Fatigue [A] *	0/12 (0%)	3/11 (27.27%)
Gait Deviation [A] *	0/12 (0%)	1/11 (9.09%)
Hyperthermia [A] *	0/12 (0%)	1/11 (9.09%)
Mucosal Inflammation [A] *	1/12 (8.33%)	0/11 (0%)
Infections and infestations		
Escherichia Infection [A] *	0/12 (0%)	1/11 (9.09%)
Oral Candidiasis [A] *	0/12 (0%)	1/11 (9.09%)
Urinary Tract Infection [A] *	1/12 (8.33%)	2/11 (18.18%)

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Injury, poisoning and procedural complications		
Fall [A] *	0/12 (0%)	1/11 (9.09%)
Lower Limb Fracture [A] *	1/12 (8.33%)	0/11 (0%)
Investigations		
Blood Lactate Dehydrogenase Increased [A] *	1/12 (8.33%)	0/11 (0%)
Positive Rombergism [A] *	0/12 (0%)	1/11 (9.09%)
Weight Decreased [A] *	1/12 (8.33%)	0/11 (0%)
Metabolism and nutrition disorders		
Decreased Appetite [A] *	3/12 (25%)	2/11 (18.18%)
Hyperglycaemia [A] *	0/12 (0%)	1/11 (9.09%)
Hypokalaemia [A] *	1/12 (8.33%)	0/11 (0%)
Hyponatraemia [A] *	0/12 (0%)	1/11 (9.09%)
Musculoskeletal and connective tissue disorders		
Back Pain [A] *	0/12 (0%)	2/11 (18.18%)
Bone Pain [A] *	0/12 (0%)	1/11 (9.09%)
Coccydynia [A] *	1/12 (8.33%)	0/11 (0%)
Muscular Weakness [A] *	0/12 (0%)	1/11 (9.09%)
Nervous system disorders		
Balance Disorder [A] *	0/12 (0%)	2/11 (18.18%)
Convulsion [A] *	1/12 (8.33%)	0/11 (0%)
Epilepsy [A] *	1/12 (8.33%)	0/11 (0%)
Headache [A] *	6/12 (50%)	6/11 (54.55%)

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Hemiparesis [A] *	1/12 (8.33%)	0/11 (0%)
Hypoaesthesia [A] *	2/12 (16.67%)	0/11 (0%)
Intracranial Pressure Increased [A] *	1/12 (8.33%)	1/11 (9.09%)
Psychomotor Skills Impaired [A] *	1/12 (8.33%)	0/11 (0%)
Somnolence [A] *	0/12 (0%)	1/11 (9.09%)
Tremor [A] *	0/12 (0%)	1/11 (9.09%)
Psychiatric disorders		
Anxiety [A] *	1/12 (8.33%)	1/11 (9.09%)
Insomnia [A] *	2/12 (16.67%)	0/11 (0%)
Renal and urinary disorders		
Hydronephrosis [A] *	1/12 (8.33%)	0/11 (0%)
Pollakiuria [A] *	1/12 (8.33%)	1/11 (9.09%)
Urinary Incontinence [A] *	1/12 (8.33%)	2/11 (18.18%)
Reproductive system and breast disorders		
Vaginal Discharge [A] *	0/12 (0%)	1/11 (9.09%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] *	0/12 (0%)	1/11 (9.09%)
Dyspnoea [A] *	0/12 (0%)	1/11 (9.09%)
Skin and subcutaneous tissue disorders		
Alopecia [A] *	4/12 (33.33%)	2/11 (18.18%)
Alopecia Areata [A] *	1/12 (8.33%)	0/11 (0%)
Dermatitis [A] *	0/12 (0%)	1/11 (9.09%)

	WBRT Followed by Standard of Care	WBRT+Capecitabine Followed by Capecitabine Maintenance
	Affected/At Risk (%)	Affected/At Risk (%)
Pain of Skin [A] *	1/12 (8.33%)	0/11 (0%)
Skin Disorder [A] *	1/12 (8.33%)	0/11 (0%)
Vascular disorders		
Hypertensive Crisis [A] *	1/12 (8.33%)	0/11 (0%)
Hypotension [A] *	1/12 (8.33%)	0/11 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (13.0)

Limitations and Caveats

Study was prematurely terminated due to an insufficient number of participants enrolled and therefore results are only based on a small sample of breast cancer participants with newly diagnosed brain metastasis and should be considered with caution.

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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