Cancer Trials Ireland CLG
RCSI House
121 St Stephen's Green
Dublin 2
D02 H903
Ireland
e: info@cancertrials.ie
t: +353 (0)1 6677211
f: +353 (0)1 6697869

17-Dec-2025

Trial **2011-003847-22**, ECOG 2809

Phase II, Randomized Study of MK-2206 - Bicalutamide Combination in Patients With Rising PSA at High-Risk of Progression After Primary Therapy.

Clinical Trial Results:

This trial was sponsored by Cancer Trials Ireland in Europe however was led and sponsored by NCI in the US. Due to differences in the reporting of specific data fields in the US and EU, certain details required for validation of trial results in EudraCT are not available to us.

We are therefore uploading and posting a summary attachment (download from ClinicalTrials.gov) together with a PDF download from EudraCT of (partial) results of the trial.

Results on CT.gov can be accessed at this link: Study Results | NCT01251861 | Bicalutamide With or Without Akt Inhibitor MK2206 in Treating Patients With Previously Treated Prostate Cancer | ClinicalTrials.gov

They correspond to what is uploaded onto EudraCT.

Cancer Trials Ireland Quality & Training Manager
Charity Regulatory Authority No. 20036676 | Revenue Number CHY12492 | Company Number 268044 a:
Cancer Trials Ireland , RCSI House, 121 St. Stephen's Green , Dublin 2 , D02 H903
t: +353 1 667 7211 | f: +353 1 669 7869 |

Clinical trial results:
E2809: Androgen Receptor Modulation
Phase II, Randomized Study of MK-2206 - Bicalutamide Combination in Patients With Rising PSA at High-Risk of Progression After Primary Therapy.

Summary

EudraCT number	2011-003847-22
Trial protocol	IE
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	CTRIAL (ICORG)11-04

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01251861
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cancer Trials Ireland
Sponsor organisation address	121 St Stephens Green, Dublin, Ireland, D02 H903
Public contact	Clinical Project Manager, Cancer Trials Ireland (formally ICORG) , 00353 16677211, info@cancertrials.ie
Scientific contact	Clinical Project Manager, Cancer Trials Ireland (formally ICORG) , 00353 16677211, info@cancertrials.ie

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 July 2018
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

This phase II trial studies how well giving bicalutamide with or without Akt inhibitor MK2206 works in treating patients with previously treated prostate cancer. Androgens can cause the growth of prostate cancer cells. Antihormone therapy, such as bicalutamide, may lessen the amount of androgens made by the body. Akt inhibitor MK2206 may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether bicalutamide is more effective with or without Akt inhibitor MK2206 in treating prostate cancer.

The main objective of the trial is to compare the two regimens on the proportion of patients with undetectable prostate-specific antigen (PSA) level (< 0.2 ng/mL) at 44 weeks.

Protection of trial subjects:

This clinical study was conducted in accordance with the EU Directive 2001/20/EC and International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP) and the appropriate regulatory requirements. The trial was also conducted in accordance with ethical principles founded in the Declaration of Helsinki.

Background therapy:

N/A

Evidence for comparator:

The primary objective is to compare 2 regimens, Arm A (observation and bicalutamide) versus Arm B (Akt inhibitor MK2206 and bicalutamide).

Actual start date of recruitment	23 December 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	10 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	United States: 106
Worldwide total number of subjects	108
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	
From 65 to 84 years	
85 years and over	

Subject disposition

Recruitment

Recruitment details:

This study was activated on December 23, 2010 and closed to accrual on September 20, 2013 with a final accrual of 108 patients from 24 participating sites.

Pre-assignment

Screening details:

Patients presenting with histologically confirmed diagnosis of prostate cancer that were previously treated for prostate cancer and display a rise in their prostate specific antigen (PSA) and who fulfill all of the inclusion criteria and none of the exclusion criteria.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Active Comparator: Arm A (observation and bicalutamide)
Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Arm type	Active comparator
Investigational medicinal product name	Bicalutamide
Investigational medicinal product code	
Other name	Casodex
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg/daily orally beginning Cycle 4 (week 13), continuously to the end of study. The tablet should be taken at approximately the same time every day.
No dose modifications allowed.

Arm title	Arm B

Arm description:

Experimental: Arm B (Akt inhibitor MK2206 and bicalutamide)
Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Patients randomized to Arm B will be treated with MK-2206 for 12 weeks followed by a 32-week combination therapy with bicalutamide and MK-2206.

Arm type	Experimental
Investigational medicinal product name	Akt Inhibitor MK2206
Investigational medicinal product code	
Other name	MK 2206, MK-2206 FREE BASE
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 Cycle = 28 days = 4 weeks. Treatment will be administered on an outpatient basis.
Cycles 1-3 (Weeks 1-12): MK-2206 200 mg once per week, orally.
Should be taken at approximately the same time each week 2 hours before or two hours after a meal.
ECG monitoring prior to and during MK2206 administration

On day 1 of cycle 1, the patient will take the medication in the clinic.
· Prior to drug administration obtain ONE ECG
Cycles 4-11 (Weeks 13-44): Continue MK-2206 200 mg once per week, orally. Start bicalutamide (Casodex) 50 mg/daily, orally, on a continuous basis.
NOTE: Patients on MK2206 alone that reach a PSA < 0.2 ng/mL by week 12 will NOT receive bicalutamide until the PSA rises to ≥ 0.2 ng/mL and is confirmed on a second determination 2 weeks later. Only after confirmation is obtained will bicalutamide be added to the patient's treatment regimen to be continued through the end of Cycle11 (Week 44).

Number of subjects in period 1	Arm A	Arm B
Started	54	54
Arm A	54	54
Arm B	54	54
Completed	36	26
Not completed	18	28
Other complicating disease	-	1
Consent withdrawn by subject	2	2
Physician decision	1	-
Adverse event, non-fatal	2	17
Disease-progression	6	-
Unknown	1	-
Never started therapy	4	1
Alternative therapy	1	-
Continued cycle beyond 18 cycles	1	-
Disease Progression	-	6
Potential interaction of drugs	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Arm A
Reporting group description:	
Active Comparator: Arm A (observation and bicalutamide) Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	
Reporting group title	Arm B
Reporting group description:	
Experimental: Arm B (Akt inhibitor MK2206 and bicalutamide) Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity. Patients randomized to Arm B will be treated with MK-2206 for 12 weeks followed by a 32-week combination therapy with bicalutamide and MK-2206.	

Reporting group values	Arm A	Arm B	Total
Number of subjects	54	54	108
Age categorical Units: Subjects			
Age continuous Units: years			
median	66	67	
full range (min-max)	47 to 81	48 to 85	-
Gender categorical Units: Subjects			
Male	54	54	108
Ethnic Origin Units: Subjects			
Black or African American	4	5	9
Asian	0	1	1
White	50	48	98

End points

End points reporting groups

Reporting group title	Arm A

Reporting group description:

Active Comparator: Arm A (observation and bicalutamide)
Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Reporting group title	Arm B

Reporting group description:

Experimental: Arm B (Akt inhibitor MK2206 and bicalutamide)
Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Patients randomized to Arm B will be treated with MK-2206 for 12 weeks followed by a 32-week combination therapy with bicalutamide and MK-2206.

Primary: The proportion of patients with undetectable PSA level (< 0.2 ng/mL) at 44 weeks

End point title	The proportion of patients with undetectable PSA level (< 0.2 ng/mL) at 44 weeks

End point description:

Results for Primary and Secondary Endpoints can be found in the summary attachment (download of results posted on ClinicalTrials.gov).

End point type	Primary

End point timeframe:

44 weeks

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are reported in a routine manner at scheduled times during a trial. Assessed every 4 weeks while on treatment and for 30 days after the end of treatment (up to about 76 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups

Reporting group title	ArmA

Reporting group description:

Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Reporting group title	ArmB

Reporting group description:

Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Serious adverse events	ArmA	ArmB	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	33 / 53 (62.26%)	
number of deaths (all causes)			
number of deaths resulting from adverse events			
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Lymphocyte count decreased			
subjects affected / exposed	0 / 50 (0.00%)	5 / 53 (9.43%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	

Neutrophil count decreased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
White blood cell count decreased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 50 (0.00%)	3 / 53 (5.66%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Thromboembolic event			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Nervous system disorders			
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Other			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	0 / 50 (0.00%)	3 / 53 (5.66%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Mucositis oral			
subjects affected / exposed	0 / 50 (0.00%)	2 / 53 (3.77%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Rash maculo-papular			
subjects affected / exposed	0 / 50 (0.00%)	20 / 53 (37.74%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 50 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 50 (0.00%)	6 / 53 (11.32%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Hyponatraemia			

subjects affected / exposed	0 / 50 (0.00%)	2 / 53 (3.77%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	
Hypophosphataemia			
subjects affected / exposed	0 / 50 (0.00%)	2 / 53 (3.77%)	
occurrences causally related to treatment / all	/	/	
deaths causally related to treatment / all	/	/	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	ArmA	ArmB	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 50 (78.00%)	52 / 53 (98.11%)	
Vascular disorders			
Hot flashes			
subjects affected / exposed	11 / 50 (22.00%)	8 / 53 (15.09%)	
occurrences (all)			
Hypertension			
subjects affected / exposed	3 / 50 (6.00%)	4 / 53 (7.55%)	
occurrences (all)			
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 50 (2.00%)	3 / 53 (5.66%)	
occurrences (all)			
Edema limbs			
subjects affected / exposed	1 / 50 (2.00%)	4 / 53 (7.55%)	
occurrences (all)			
Fatigue			
subjects affected / exposed	16 / 50 (32.00%)	33 / 53 (62.26%)	
occurrences (all)			
Fever			
subjects affected / exposed	0 / 50 (0.00%)	4 / 53 (7.55%)	
occurrences (all)			
Reproductive system and breast disorders			

Breast pain subjects affected / exposed occurrences (all)	26 / 50 (52.00%)	14 / 53 (26.42%)	
Gynaecomastia subjects affected / exposed occurrences (all)	21 / 50 (42.00%)	11 / 53 (20.75%)	
Reproductive system and breast-other subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	3 / 53 (5.66%)	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	3 / 53 (5.66%)	
Nasal congestion subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	1 / 53 (1.89%)	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	3 / 53 (5.66%)	
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	3 / 53 (5.66%)	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	6 / 53 (11.32%)	
Creatinine increased subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	10 / 53 (18.87%)	
Lymphocyte count decreased subjects affected / exposed occurrences (all)	5 / 50 (10.00%)	12 / 53 (22.64%)	
Neutrophil count decreased			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	3 / 53 (5.66%)	
Platelet count decreased subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	8 / 53 (15.09%)	
Weight loss subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	4 / 53 (7.55%)	
White blood cell decreased subjects affected / exposed occurrences (all)	4 / 50 (8.00%)	9 / 53 (16.98%)	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	1 / 50 (2.00%)	4 / 53 (7.55%)	
Dysgeusia subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	6 / 53 (11.32%)	
Headache subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	6 / 53 (11.32%)	
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	11 / 53 (20.75%)	
Eye disorders			
Vision blurred subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	3 / 53 (5.66%)	
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	4 / 50 (8.00%)	3 / 53 (5.66%)	
Constipation subjects affected / exposed occurrences (all)	1 / 50 (2.00%)	8 / 53 (15.09%)	
Diarrhoea			

subjects affected / exposed occurrences (all)	1 / 50 (2.00%)	26 / 53 (49.06%)	
Dry mouth subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	6 / 53 (11.32%)	
Dyspepsia subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	6 / 53 (11.32%)	
Flatulence subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	5 / 53 (9.43%)	
Mucositis oral subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	10 / 53 (18.87%)	
Nausea subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	10 / 53 (18.87%)	
Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	17 / 53 (32.08%)	
Photosensitivity subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	3 / 53 (5.66%)	
Pruritus subjects affected / exposed occurrences (all)	2 / 50 (4.00%)	24 / 53 (45.28%)	
Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 50 (2.00%)	29 / 53 (54.72%)	
Skin and subcutaneous tissue disorders - Other subjects affected / exposed occurrences (all)	1 / 50 (2.00%)	5 / 53 (9.43%)	
Musculoskeletal and connective tissue disorders			

Arthralgia subjects affected / exposed occurrences (all)	3 / 50 (6.00%)	2 / 53 (3.77%)	
Metabolism and nutrition disorders Anorexia subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	10 / 53 (18.87%)	
Hyperglycaemia subjects affected / exposed occurrences (all)	7 / 50 (14.00%)	23 / 53 (43.40%)	
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	5 / 53 (9.43%)	
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%)	3 / 53 (5.66%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 April 2012	Amendment 1 - Protocol Version date 28-Feb-2012 Updates included: -Update to Biochemical failure and progression guidelines -Update to PSA calculation guidelines -Update to Eligibility criteria -Update to Treatment Arm B -Update to ECG monitoring instructions -Update to radiologic evaluation requirements for follow up -Administrative changes
04 May 2012	Amendment 2 Updates included: - update to reflect the use of a SPEER (Special Protocol Exceptions to Expedited Reporting). - CAEPR (Comprehensive Adverse Events and Potential Risks List) for MK-2206 updated to version 2.0. The ASAEL (Agent Specific Adverse Event List) column has been replaced with a Specific Protocol Exceptions to Expedited Reporting (SPEER) column. - MK-2206 risk list replaced with updated version - Administrative changes
21 June 2012	Amendment 3 Updates included: - New eligibility criterion added regarding prior treatment with targeted agent(s) and timing of discontinuation. - Revised language for reporting pregnancies. - Clarification on ECG requirements before first treatment. - Update to study table. - Administrative changes.
29 November 2012	Amendment 4 Changes included: - Update made to PSA1 definition from “any PSA value that shows an increase over the threshold PSA” to “any PSA value that is equal or greater than the threshold PSA.” - Updated ECG Monitoring parameters with revised guidelines. - Updated pregnancy clause with revised pregnancy reporting requirements. - Replaced list of risks for MK-2206 following CAEPR table with updated list. - Administrative changes

11 April 2013	Amendment 5 Changes included: - Update to clarify timing of PSA evaluations. - Updated to clarify prior and concurrent malignancy exclusion requirement as well as exceptions. - Updated Dose modification section with revised timing requirement from "within 2 weeks" to "within 42 days." Additionally, revised wording of "leading to treatment delay of >2 weeks" to "leading to treatment delay of >42 days." - Updated instructions for grade 1 and 2 toxicities. - Toxicity table revised - Update to dose modification subsection titled "Drug induced maculo-papular rash treatment guide' - Revised Time to PSA progression to reflect consistent requirements throughout protocol. - Revised Drug formulation section with updated language provided by the NCI. - Table of CYP3A4 Inhibitors replaced with updated list. - Table of CYP3A4 Inducers replaced with updated list. - Administrative changes
03 September 2013	Amendment 6 and Amendment 7 Changes include: - Update to eligibility criterion regarding glucose monitoring. - Update to ECOG and Protocol Specific expedited reporting requirements - Replaced MK-2206 CAEPR with a new version. - Revision to anti-pruritic medication to add specifics for acceptable corticosteroids. - Update to glucose monitoring for patients with diabetes. - Clarification of MK-2206 tablet supply policy. - Administrative changes
20 October 2014	Amendment 8 Changes include: - Update to AdEERS system to the CTEP-AERS system. - Update to pregnancy reporting requirements - Update to tablet supply - Update to Biological Material Submission section - Administrative changes
20 October 2014	Amendment 9 Changes include: - Update to more clearly define undetectable PSA.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Not specified.

Notes:

Record 1 of 1

Active, not recruiting

Bicalutamide With or Without Akt Inhibitor MK2206 in Treating Patients With Previously Treated Prostate Cancer

ClinicalTrials.gov ID NCT01251861

Sponsor National Cancer Institute (NCI)

Information provided by National Cancer Institute (NCI) (Responsible Party)

Last Update Posted 2025-12-11

Results Posted Tab

Results Overview

Conditions

Recurrent Prostate Carcinoma | Stage I Prostate Cancer AJCC v7 | Stage IIA Prostate Cancer AJCC v7

Stage IIB Prostate Cancer AJCC v7 Stage III Prostate Cancer AJCC v7

Intervention/Treatment

- Drug: Akt Inhibitor MK2206
- Drug: Bicalutamide
- Other: Clinical Observation
- Other: Laboratory Biomarker Analysis

Other Study ID Numbers

- NCI-2011-02648
- NCI-2011-02648 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))

Show 8 more study numbers

Study Design

Allocation: Randomized
Interventional Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Results Point of Contact

Name/Title: Study Statistician
Organization: ECOG-ACRIN Statistical Office
Phone: 617-632-3012
Email: eatrials@jimmy.harvard.edu

Enrollment (Actual)

108

Study Type

Interventional

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2010-12-01

First Posted (Estimated)

2010-12-02

Results Reporting Dates

Results First Submitted

2019-09-25

Results First Posted

2019-12-05

Study Record Updates

Last Update Posted (Estimated)

2025-12-11

Last Verified

2025-06

Participant Flow

Recruitment Details

This study was activated on December 23, 2010 and closed to accrual on September 20, 2013 with a final accrual of 108 patients from 24 participating sites.

Pre-assignment Details

[Not Specified]

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Period Title: **Overall Study**

Started	54	54
Pts Who Received Protocol Therapy	50	53

Pts w/ Follow-up PSA Lower Than Baseline	49	47
Pts With PSA Response	44	36
Completed	36	26
Not Completed	18	28

Reason Not Completed

Disease progression	6	6
Adverse Event	2	17
Withdrawal by Subject	2	2
Alternative therapy	1	0
Other complicating disease	0	1
Physician Decision	1	0
Continued treatment beyond 18 cycles	1	0
Other	1	0
Never started therapy	4	1
Potential interaction of drugs	0	1

Baseline Characteristics

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)	Total
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Total of all reporting groups
Overall Number of Baseline Participants	54	54	108
Baseline Analysis Population Description	All randomized patients are included in the analysis.		

Expand all / Collapse all

Age, Continuous

Median (Full Range) | Unit of measure: years

Number Analyzed	54 participants	54 participants	108 participants
	66	67	66

	(47 to 81)	(48 to 85)	(47 to 85)

Sex: Female, Male

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	54 participants	54 participants	108 participants
Female	0 0.0%	0 0.0%	0 0.0%
Male	54 100.0%	54 100.0%	108 100.0%

Race (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	54 participants	54 participants	108 participants
American Indian or Alaska Native	0 0.0%	0 0.0%	0 0.0%
Asian	0 0.0%	1 1.9%	1 0.9%
Native Hawaiian or Other Pacific Islander	0 0.0%	0 0.0%	0 0.0%
Black or African American	4 7.4%	5 9.3%	9 8.3%
White	50 92.6%	48 88.9%	98 90.7%
More than one race	0 0.0%	0 0.0%	0 0.0%

Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%

Outcome Measures

Expand all / Collapse all

1. The Proportion of Patients With Undetectable PSA Level (< 0.2 ng/mL) at 44 Weeks

Type: Primary | Time Frame: 44 weeks

Description	The proportion of patients with undetectable PSA level (< 0.2 ng/mL) at 44 weeks, defined as number of patients with undetectable PSA level at 44 weeks divided by number of patients randomized.
Time Frame	44 weeks
Analysis Population Description	All randomized patients are included in this analysis.

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54
Measure Type: Number (80% Confidence Interval) | Unit of Measure: proportion of participants	0.093 (0.046 to 0.165)	0.148 (0.088 to 0.23)

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm A (Observation and Bicalutamide), Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Comments	[Not Specified]
Type of Statistical Test	Superiority
Comments	[Not Specified]

Statistical Test of Hypothesis

P-Value	0.28
Comments	one-sided
Method	Fisher Exact
Comments	[Not Specified]

2. Proportion of Patients With PSA Decline > 85% at 44 Weeks

Type: Secondary | Time Frame: 44 weeks

Description	Proportion of patients with PSA decline > 85% at 44 weeks from baseline, defined as number of patients with PSA decline > 85% at 44 weeks from baseline divided by number of patients randomized.
Time Frame	44 weeks
Analysis Population Description	All randomized patients are included in the analysis.

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54
Measure Type: Number (95% Confidence Interval) | Unit of Measure: proportion of participants	0.296 (0.18 to 0.436)	0.426 (0.292 to 0.568)

3. Proportion of Patients With PSA Response

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	PSA complete response (CR) is defined as a PSA <0.2 ng/mL confirmed on two consecutive additional determinations taken at least 4 weeks apart. PSA partial response (PR) is defined as a reduction in PSA ≥ 50% from baseline without evidence of progression (confirmed on two consecutive additional determinations taken at least 4 weeks apart). Either CR or PR is considered as a PSA response.
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years
Analysis Population Description	All randomized patients

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54
Measure Type: Number (95% Confidence Interval) | Unit of Measure: proportion of participants	0.815 (0.686 to 0.908)	0.667 (0.525 to 0.789)

4. Time to PSA Progression

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	Time to PSA progression was defined as the time from randomization to PSA progression or date of last disease assessment showing progression-free. Development of clinical progression is also considered as an event. • For patients (pts) who achieved a ≥ 50% decline in PSA (confirmed on two consecutive determinations taken at least 4 weeks apart), progression is defined as an increase in PSA by 50% above baseline or nadir, whichever is lowest, confirmed by a 2nd PSA rise at least two weeks later. The PSA rise must be >= 5 ng/mL. • For pts with an undetectable PSA nadir (< 0.2 ng/mL confirmed on two consecutive determinations taken at least 4 weeks apart), progression is defined as PSA ≥ 0.2 ng/mL confirmed by a 2nd PSA rise at least 2 weeks later.

	• For pts whose PSA has not decreased by 50%, progression is defined as an increase in PSA of ≥ 50% of baseline or nadir PSA, whichever is lowest, confirmed by a repeat PSA at least 2 weeks later. The PSA must have risen by >= 5 ng/mL	
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years	
Analysis Population Description	All randomized patients	
Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54
Median (95% Confidence Interval) | Unit of Measure: months	25.8 (21.0 to 37.7)	24.3 (19.1 to 30.1)

5. Time to PSA Nadir

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	Time to PSA nadir was defined as the time from randomization to the date that PSA nadir, the lowest PSA value achieved after randomization, was documented. This analysis was performed among patients whose PSA level decreased after randomization compared to baseline.	
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years	
Analysis Population Description	Only patients who received protocol therapy and had follow-up PSA level lower than baseline PSA were included.	
Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	49	47
Median (Full Range) | Unit of Measure: months	7.7 (1.1 to 22.0)	6.7 (0.3 to 19.3)

6. Duration of PSA Response

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	Duration of PSA response was defined as the time from the date PSA criteria were met for complete response (CR) or partial response (PR), whichever status was recorded first, to the date of PSA progression. Patients without documented PSA progression were censored at the date of last disease assessment. Duration of PSA response is analyzed among responders (PSA CR or PR).

Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years	
Analysis Population Description	Patients with PSA response (CR or PR)	
Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	44	36
Median (95% Confidence Interval) | Unit of Measure: months	20.6 (17.0 to 34.7)	25.3 (17.6 to 37.5)

7. PSA Slope Prior to Randomization

Type: Secondary | Time Frame: Baseline (pre-randomization)

Description	PSA slopes were assessed by multiple PSA values prior to randomization. Linear regression was used to calculate PSA slope using natural log-transformed PSA values on the time of PSA measurements for each patient.
Time Frame	Baseline (pre-randomization)

Analysis Population Description	All randomized patients	
Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54
Mean (Standard Deviation) | Unit of Measure: ln(PSA)/month	0.20 (0.16)	0.20 (0.13)

8. PSA Slope After Randomization and Before Starting Bicalutamide

Type: Secondary | Time Frame: After randomization and prior to starting bicalutamide

Description	PSA slopes were assessed by multiple PSA values from randomization to starting bicalutamide treatment. Linear regression was used to calculate PSA slope using natural log-transformed PSA values on the time of PSA measurements for each patient.
Time Frame	After randomization and prior to starting bicalutamide
Analysis Population Description	Patients with follow-up PSA measurement before starting bicalutamide.

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	49	53
Mean (Standard Deviation) | Unit of Measure: ln(PSA)/month	0.10 (0.14)	0.06 (0.23)

9. PSA Slope After Starting Bicalutamide Treatment

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	PSA slopes were assessed by multiple PSA values after starting bicalutamide treatment. Linear regression was used to calculate PSA slope using natural log-transformed PSA values on the time of PSA measurements for each patient.
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years
Analysis Population Description	Patients with follow-up PSA measurement after starting bicalutamide.

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	48	42
Mean (Standard Deviation) | Unit of Measure: ln(PSA)/month	-0.57 (0.96)	-0.60 (0.57)

10. The Association Between Gleason Score and PSA Response

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	The association between PSA response (responder vs non-responder) and Gleason score (<7, 7 vs. >7) was evaluated by logistic regression with adjustment for treatment assignment. Based on the biopsy sample, a Gleason grade is assigned to the most predominant pattern in the biopsy and a second Gleason grade is assigned to the second most predominant pattern. The two grades will then be added together to determine the Gleason score. Gleason scores range from 2-10. The higher the Gleason score, the more aggressive the cancer is likely to be.
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years
Analysis Population Description	All randomized patients

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54

Gleason score <7

Number Analyzed	10 participants	10 participants
Responder ✻Measure Type: Count of Participants | Unit of Measure: Participants	9 90.0%	7 70.0%
Non-responder *	1 10.0%	3 30.0%

Gleason score =7

Number Analyzed	25 participants	23 participants
Responder *	20 80.0%	17 73.9%
Non-responder *	5 20.0%	6 26.1%

Gleason score >7

Number Analyzed	19 participants	21 participants

Responder *	15 78.9%	12 57.1%
Non-responder *	4 21.1%	9 42.9%

* Measure Type: Count of Participants | Unit of Measure: Participants

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm A (Observation and Bicalutamide), Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Comments	The association between PSA response (responder vs non-responder) and Gleason score (<7, 7 vs. >7) was evaluated by logistic regression with adjustment for treatment assignment.
Type of Statistical Test	Other
Comments	The association between PSA response (responder vs non-responder) and Gleason score (<7, 7 vs. >7) was evaluated by logistic regression with adjustment for treatment assignment.

Statistical Test of Hypothesis

P-Value	0.50
Comments	p-value based on logistic regression with adjustment for treatment assignment
Method	Regression, Logistic
Comments	[Not Specified]

11. The Association Between Prior Hormonal Therapy and PSA Response

Type: Secondary | Time Frame: Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years

Description	The association between PSA response (responder vs non-responder) and prior hormonal therapy (yes vs. no) was evaluated by logistic regression with adjustment for treatment assignment.
Time Frame	Assessed every 3 months for 2 years, every 6 months for 3 years, and then annually up to 10 years
Analysis Population Description	All randomized patients

Arm/Group Title	Arm A (Observation and Bicalutamide)	Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.
Overall Number of Participants Analyzed	54	54

No prior hormonal therapy

Number Analyzed	31 participants	29 participants
Responder ✻Measure Type: Count of Participants | Unit of Measure: Participants	28 90.3%	19 65.5%
Non-responder *	3 9.7%	10 34.5%

Received prior hormonal therapy

Number Analyzed	23 participants	25 participants
Responder *	16 69.6%	17 68.0%
Non-responder *	7 30.4%	8 32.0%

* Measure Type: Count of Participants | Unit of Measure: Participants

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm A (Observation and Bicalutamide), Arm B (Akt Inhibitor MK2206 and Bicalutamide)
Comments	The association between PSA response (responder vs non-responder) and prior hormonal therapy (yes vs. no) was evaluated by logistic regression with adjustment for treatment assignment.
Type of Statistical Test	Other
Comments	The association between PSA response (responder vs non-responder) and prior hormonal therapy (yes vs. no) was evaluated by logistic regression with adjustment for treatment assignment.
Statistical Test of Hypothesis	P-Value
P-Value	0.28
Comments	p-value based on logistic regression with adjustment for treatment assignment
Method	Regression, Logistic
Comments	[Not Specified]

T2: Samples of the Primary Tumor Specimen Will be Retrieved for Banking and Future Analysis of the Molecular Profile of the Primary PC Tissues With Emphasis on the AR and Akt Upstream and Downstream Signaling Pathways.

Type: Other Pre-specified | Time Frame: Baseline

Description	Biospecimen banking for future analysis, no data to be reported
Time Frame	Baseline
Analysis Population Description	[Not Specified]

Outcome Measure Data Not Reported

Adverse Events

Time Frame
Assessed every 4 weeks while on treatment and for 30 days after the end of treatment (up to about 76 weeks)

Adverse Event Reporting Description
All-cause mortality was monitored in all randomized patients and all other adverse events were assessed in participants who received treatment.

Arm/Group Title	Arm A (Observation + Bicalutamide)	Arm B (MK-2206 + Bicalutamide)
Arm/Group Description	Patients undergo observation on weeks 1-12. Patients then receive bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.	Patients receive Akt inhibitor MK2206 PO once per week on weeks 1-44 and bicalutamide PO QD on weeks 13-44. Patients with a PSA decline of >= 50% may continue on Akt inhibitor MK2206 and bicalutamide until week 72 in the absence of disease progression or unacceptable toxicity.

Expand all / Collapse all

All-Cause Mortality

Arm/Group Title	Arm A (Observation + Bicalutamide)	Arm B (MK-2206 + Bicalutamide)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	9/54 (16.67%)	9/54 (16.67%)

Serious Adverse Events

Arm/Group Title	Arm A (Observation + Bicalutamide)	Arm B (MK-2206 + Bicalutamide)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	1/50 (2.00%)	33/53 (62.26%)
Blood and lymphatic system disorders		
Anemia †1	0/50 (0.00%)	1/53 (1.89%)
Blood and lymphatic disorders - Other †1	0/50 (0.00%)	1/53 (1.89%)
Gastrointestinal disorders		
Hemorrhoids †1	0/50 (0.00%)	1/53 (1.89%)
Mucositis oral †1	0/50 (0.00%)	2/53 (3.77%)
General disorders		
Fatigue †1	0/50 (0.00%)	3/53 (5.66%)
Investigations		
Alanine aminotransferase increased †1	1/50 (2.00%)	0/53 (0.00%)
Aspartate aminotransferase increased †1	1/50 (2.00%)	0/53 (0.00%)

Lymphocyte count decreased †1	0/50 (0.00%)	5/53 (9.43%)
Neutrophil count decreased †1	0/50 (0.00%)	1/53 (1.89%)
White blood cell decreased †1	0/50 (0.00%)	1/53 (1.89%)
Metabolism and nutrition disorders		
Hyperglycemia †1	0/50 (0.00%)	6/53 (11.32%)
Hyponatremia †1	0/50 (0.00%)	2/53 (3.77%)
Hypophosphatemia †1	0/50 (0.00%)	2/53 (3.77%)
Musculoskeletal and connective tissue disorders		
Pain in extremity †1	0/50 (0.00%)	1/53 (1.89%)
Nervous system disorders		
Peripheral sensory neuropathy †1	0/50 (0.00%)	1/53 (1.89%)
Skin and subcutaneous tissue disorders		
Pruritus †1	0/50 (0.00%)	1/53 (1.89%)
Rash maculo-papular †1	0/50 (0.00%)	20/53 (37.74%)

Vascular disorders

Hypertension †1	0/50 (0.00%)	3/53 (5.66%)
Thromboembolic event †1	0/50 (0.00%)	1/53 (1.89%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE 4.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
Arm/Group Title	Arm A (Observation + Bicalutamide)	Arm B (MK-2206 + Bicalutamide)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	39/50 (78.00%)	52/53 (98.11%)

Blood and lymphatic system disorders

Anemia †1	3/50 (6.00%)	11/53 (20.75%)

Eye disorders

Blurred vision †1	0/50 (0.00%)	3/53 (5.66%)

Gastrointestinal disorders

Abdominal pain †1	4/50 (8.00%)	3/53 (5.66%)
Constipation †1	1/50 (2.00%)	8/53 (15.09%)
Diarrhea †1	1/50 (2.00%)	26/53 (49.06%)
Dry mouth †1	0/50 (0.00%)	6/53 (11.32%)
Dyspepsia †1	2/50 (4.00%)	6/53 (11.32%)
Flatulence †1	0/50 (0.00%)	5/53 (9.43%)
Mucositis oral †1	0/50 (0.00%)	10/53 (18.87%)
Nausea †1	3/50 (6.00%)	10/53 (18.87%)
General disorders		
Chills †1	1/50 (2.00%)	3/53 (5.66%)
Edema limbs †1	1/50 (2.00%)	4/53 (7.55%)
Fatigue †1	16/50 (32.00%)	33/53 (62.26%)
Fever †1	0/50 (0.00%)	4/53 (7.55%)
Investigations		
Alanine aminotransferase increased †1	2/50 (4.00%)	3/53 (5.66%)

Aspartate aminotransferase increased †1	3/50 (6.00%)	6/53 (11.32%)
Creatinine increased †1	2/50 (4.00%)	10/53 (18.87%)
Lymphocyte count decreased †1	5/50 (10.00%)	12/53 (22.64%)
Neutrophil count decreased †1	0/50 (0.00%)	3/53 (5.66%)
Platelet count decreased †1	2/50 (4.00%)	8/53 (15.09%)
Weight loss †1	0/50 (0.00%)	4/53 (7.55%)
White blood cell decreased †1	4/50 (8.00%)	9/53 (16.98%)

Metabolism and nutrition disorders

Anorexia †1	0/50 (0.00%)	10/53 (18.87%)
Hyperglycemia †1	7/50 (14.00%)	23/53 (43.40%)
Hypocalcemia †1	0/50 (0.00%)	3/53 (5.66%)
Hypophosphatemia †1	0/50 (0.00%)	5/53 (9.43%)

Musculoskeletal and connective tissue disorders

Arthralgia †1	3/50 (6.00%)	2/53 (3.77%)
Nervous system disorders		
Dizziness †1	1/50 (2.00%)	4/53 (7.55%)
Dysgeusia †1	0/50 (0.00%)	6/53 (11.32%)
Headache †1	3/50 (6.00%)	6/53 (11.32%)
Psychiatric disorders		
Insomnia †1	2/50 (4.00%)	3/53 (5.66%)
Reproductive system and breast disorders		
Breast pain †1	26/50 (52.00%)	14/53 (26.42%)
Gynecomastia †1	21/50 (42.00%)	11/53 (20.75%)
Reproductive system and breast - Other †1	2/50 (4.00%)	3/53 (5.66%)
Respiratory, thoracic and mediastinal disorders		
Dyspnea †1	0/50 (0.00%)	3/53 (5.66%)
Nasal congestion †1	3/50 (6.00%)	1/53 (1.89%)
Skin and subcutaneous tissue disorders		
Dry skin †1	2/50 (4.00%)	17/53 (32.08%)

Photosensitivity †1	0/50 (0.00%)	3/53 (5.66%)
Pruritus †1	2/50 (4.00%)	24/53 (45.28%)
Rash maculo-papular †1	1/50 (2.00%)	29/53 (54.72%)
Skin and subcutaneous tissue - Other †1	1/50 (2.00%)	5/53 (9.43%)

Vascular disorders

Hot flashes †1	11/50 (22.00%)	8/53 (15.09%)
Hypertension †1	3/50 (6.00%)	4/53 (7.55%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE 4.0

Limitations and Caveats

[Not Specified]

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

National Cancer Institute (NCI)

Investigators

- Principal Investigator: Anna C Ferrari, ECOG-ACRIN Cancer Research Group

More Information

Record History

Certain Agreements

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

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