Trial record **1 of 1** for: TRITON 3 CO-338-063

Previous Study | Return to List | Next Study

A Study of Rucaparib Versus Physician's Choice of Therapy in Patients With Metastatic Castration-resistant Prostate Cancer and Homologous Recombination Gene Deficiency (TRITON3)

ClinicalTrials.gov Identifier: NCT02975934

Recruitment Status: Recruiting
First Posted: November 29, 2016
Last Update Posted: August 20, 2018

See Contacts and Locations

Sponsor:
Clovis Oncology, Inc.

Collaborator:
Foundation Medicine

Information provided by (Responsible Party):
Clovis Oncology, Inc.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:
The purpose of this study is to determine how patients with metastatic castration-resistant prostate cancer, and evidence of a homologous recombination gene deficiency, respond to treatment with rucaparib versus treatment with physician's choice of abiraterone acetate, enzalutamide, or docetaxel.

Condition or disease	Intervention/treatment	Phase
Metastatic Castration Resistant Prostate Cancer	Drug: Rucaparib Drug: Abiraterone acetate or Enzalutamide or Docetaxel	Phase **3**

Study Design

Go to

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	400 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	**TRITON3**: A Multicenter, Randomized, Open Label Phase **3** Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency
Study Start Date:	January 2017
Estimated Primary Completion Date:	February 2022
Estimated Study Completion Date:	April 2022

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics:
Progressive external ophthalmoplegia Prostate cancer

MedlinePlus related topics: Prostate Cancer

Drug Information available for: Docetaxel Abiraterone acetate Rucaparib Enzalutamide

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Rucaparib Oral rucaparib (monotherapy).	Drug: Rucaparib Rucaparib will be administered daily. Other Name: CO-338
Active Comparator: Abiraterone acetate or Enzalutamide or Docetaxel Oral abiraterone acetate (monotherapy, given in combination with prednisone). Oral enzalutamide (monotherapy). Intravenous docetaxel (monotherapy, given in combination with prednisone or prednisolone).	Drug: Abiraterone acetate or Enzalutamide or Docetaxel Abiraterone acetate and enzalutamide will be administered daily. Docetaxel will be administered every **3** weeks. Other Name: Zytiga (abiraterone acetate) or Xtandi (enzalutamide) or Taxotere (docetaxel)

Outcome Measures

Go to

Primary Outcome Measures:

1. Radiographic Progression-free Survival (rPFS) [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]

Secondary Outcome Measures :

1. Objective Response Rate (ORR) [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
2. Duration of Response (DOR) [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
3. Time to Prostate Specific Antigen (PSA) Progression [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
4. PSA Response [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
5. Change in Patient-reported Outcome (PRO) [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
6. Clinical Benefit Rate (CBR), defined as the percentage of patients with a complete response (CR), partial response (PR), and stable disease (SD) according to modified RECIST Version 1.1 with no progression in bone per PCWG**3** criteria [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
7. Overall Survival [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
8. Trough plasma PK (Cmin) of rucaparib based on sparse sampling [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]
9. Number of participants with Adverse Events (AEs) as a measure of safety and tolerability [Time Frame: From enrollment to primary completion of study (up to approximately 5 years)]

   Composite assessment of treatment-emergent AEs, including laboratory abnormalities, vital sign abnormalities, electrocardiogram (ECG) abnormalities, physical examination abnormalities and ECOG abnormalities

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	Male
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Be 18 years old at the time the informed consent is signed

- Have a histologically or cytologically confirmed adenocarcinoma or poorly differentiated carcinoma of the prostate
- Be surgically or medically castrated, with serum testosterone levels of ≤ 50 ng/dL (1.73 nM)
- Be eligible for treatment with physician's choice of comparator treatment (abiraterone acetate, enzalutamide or docetaxel)
- Experienced disease progression after having received 1 prior next generation androgen receptor-targeted therapy for castration-resistant disease
- Have a deleterious mutation in a BRCA1/2 or ATM gene

Exclusion Criteria:

- Active second malignancy, with the exception of curatively treated non melanoma skin cancer, carcinoma in situ, or superficial bladder cancer
- Prior treatment with any PARP inhibitor
- Prior treatment with chemotherapy for metastatic castration-resistant prostate cancer
- Symptomatic and/or untreated central nervous system metastases
- Pre-existing duodenal stent and/or any gastrointestinal disorder or defect that would, in the opinion of the investigator, interfere with absorption of study drug

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02975934***

Contacts

Contact: Clovis Oncology Clinical Trial Navigation Service	1-855-262-3040 (USA)	clovistrials@emergingmed.
Contact: Clovis Oncology Clinical Trial Navigation Service	1-303-625-5160 (ex-USA)	clovistrials@emergingmed.

Show 90 Study Locations

Sponsors and Collaborators

Clovis Oncology, Inc.

Foundation Medicine

More Information

Go to

Responsible Party:	Clovis Oncology, Inc.
ClinicalTrials.gov Identifier:	NCT02975934 History of Changes
Other Study ID Numbers:	**CO-338-063**
First Posted:	November 29, 2016 Key Record Dates
Last Update Posted:	August 20, 2018
Last Verified:	August 2018

Keywords provided by Clovis Oncology, Inc.:

TRITON
CRPC
PARP inhibitor
PARPi
BRCA
ATM
HRD
homologous recombination
DNA repair
DNA defect
DNA anomaly
germline
somatic

Additional relevant MeSH terms:

Prostatic Neoplasms
Genital Neoplasms, Male
Urogenital Neoplasms
Neoplasms by Site
Neoplasms
Genital Diseases, Male
Prostatic Diseases
Docetaxel
Rucaparib
Abiraterone Acetate
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Steroid Synthesis Inhibitors
Enzyme Inhibitors
Hormone Antagonists
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Cytochrome P-450 Enzyme Inhibitors
Poly(ADP-ribose) Polymerase Inhibitors