Trial record 1 of 1 for: nct01867710
Previous Study | Return to List | Next Study

Abiraterone With Different Steroid Regimens for Side Effect Related to Mineralcorticoid Excess Prevention in Prostate Cancer Prior to Chemotherapy

This study is ongoing, but not recruiting participants.

Sponsor:
Janssen Pharmaceutica N.V., Belgium

Information provided by (Responsible Party):
Janssen Pharmaceutica N.V., Belgium

ClinicalTrials.gov Identifier:
NCT01867710

First received: May 30, 2013
Last updated: October 5, 2016
Last verified: October 2016
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The purpose of the study is to determine the safety and clinical benefit of the combinations of abiraterone acetate and prednisone or abiraterone and dexamethasone in prostate cancer patients. Prednisone will be given at one of three different dose schedules. Dexamethasone will be given at one dose schedule. This will include looking at what side effects occur and how often they occur. In addition the impact of the study drug on quality of life and pain will be evaluated. The study will also collect data on subsequent treatment of patients after they come off the study drug (up to a maximum of 5 years after the study starts). By analyzing blood samples, the study aims to identify if some markers could help to understand if the treatment with abiraterone is effective and also help to understand if patients can become resistant.

Condition	Intervention	Phase
Prostate Cancer	Drug: Abiraterone Acetate Drug: Prednisone 5 mg twice daily Drug: Prednisone 5 mg once daily Drug: Prednisone 2.5 mg twice daily Drug: Dexamethasone 0.5 mg once daily	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized Phase 2 Study Evaluating Abiraterone Acetate With Different Steroid Regimens for Preventing Symptoms Associated With Mineralocorticoid Excess in Asymptomatic, Chemotherapy-naïve and Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients

Resource links provided by NLM:

Genetics Home Reference related topics: prostate cancer

MedlinePlus related topics: Cancer Prostate Cancer Steroids

Drug Information available for: Prednisone Abiraterone acetate

Genetic and Rare Diseases Information Center resources: Hyperadrenalism

U.S. FDA Resources

Further study details as provided by Janssen Pharmaceutica N.V., Belgium:

Primary Outcome Measures:

- Percentage of Participants Experiencing Neither of the 2 Mineralocorticoid Excess Toxicity During the First 24 Weeks of Treatment [Time Frame: Week 24] [Designated as safety issue: Yes]

  No mineralocorticoid excess is defined as experiencing neither of the 2 mineralocorticoid excess toxicities, that is, neither hypokalemia nor hypertension.

Secondary Outcome Measures:

- Percentage of Participants With Confirmed Prostate Specific Antigen (PSA) Response Rate [Greater Than or Equal to (>=) 50 Percent (%) Decline From Baseline] at Week 12 [Time Frame: Week 12] [Designated as safety issue: No]

  The PSA response is defined as a >= 50% decline from baseline according to the adapted Prostate Cancer Working Group 2 (PCWG2) criteria. For a PSA response to be confirmed, an additional PSA measurement obtained 4 or more weeks later has to show >=50% decline from baseline.

Enrollment:	164
Study Start Date:	July 2013
Estimated Study Completion Date:	July 2018
Primary Completion Date:	April 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: AA + prednisone 5 mg twice daily Abiraterone acetate in combination with prednisone 5 mg twice daily	Drug: Abiraterone Acetate Type = exact number; unit = mg; number = 1000; form = tablet; route = oral; taken as four 250 mg tablets once daily at least 2 hours after eating and no food should be eaten for at least 1 hour after taking the tablets. Drug: Prednisone 5 mg twice daily type = exact number; unit = mg; number = 5; form = tablet; route = oral; taken twice daily, the first dose in the morning after a meal and the second dose after a minimum interval of 8 hours in the late afternoon or early evening, after a meal
Experimental: AA + prednisone 5 mg once daily Abiraterone acetate in combination with prednisone 5 mg once daily dose	Drug: Abiraterone Acetate Type = exact number; unit = mg; number = 1000; form = tablet; route = oral; taken as four 250 mg tablets once daily at least 2 hours after eating and no food should be eaten for at least 1 hour after taking the tablets. Drug: Prednisone 5 mg once daily type = exact number; unit = mg; number = 5; form = tablet; route = oral; taken once daily, in the morning after a meal
Experimental: AA + prednisone 2.5 mg twice daily Abiraterone acetate in combination with prednisone 2.5 mg twice daily	Drug: Abiraterone Acetate Type = exact number; unit = mg; number = 1000; form = tablet; route = oral; taken as four 250 mg tablets once daily at least 2 hours after eating and no food should be eaten for at least 1 hour after taking the tablets. Drug: Prednisone 2.5 mg twice daily type = exact number; unit = mg; number = 2.5; form = tablet; route = oral; taken twice daily, the first dose in the morning after a meal and the second dose after a minimum interval of 8 hours in the late afternoon or early evening, after a meal
Experimental: AA + dexamethasone 0.5 mg once daily Abiraterone acetate in combination with dexamethasone 0.5 mg once daily	Drug: Abiraterone Acetate Type = exact number; unit = mg; number = 1000; form = tablet; route = oral; taken as four 250 mg tablets once daily at least 2 hours after eating and no food should be eaten for at least 1 hour after taking the tablets. Drug: Dexamethasone 0.5 mg once daily type = exact number; unit = mg; number = 0.5; form = tablet; route = oral; taken once daily, in the morning after breakfast

Show Detailed Description

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)

Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Have a histologically or cytologically confirmed adenocarcinoma of the prostate Have metastatic disease documented by positive bone scan or by computed tomography or magnetic resonance imaging Have prostate cancer progression documented by prostate specific antigen according to Prostate Cancer Working Group 2 or radiographic progression according to modified RECIST (response evaluation criteria in solid tumors, v1.1) criteria Be asymptomatic from prostate cancer. A score of 0-1 on BPI-SF Question #3 (worst pain in last 24 hours) will be considered asymptomatic Be surgically or medically castrated, with testosterone levels of <50 ng/dL (<2.0 nmol/L). If the subject is being treated with luteinizing hormone releasing hormone (LHRH) agonists or antagonists (subjects who have not undergone orchiectomy), this therapy must have been initiated at least 4 weeks prior to Day 1, Cycle 1 and must be continued throughout the study.

Exclusion Criteria:

Has a history of pituitary or adrenal dysfunction Has an active infection or other medical condition that would contraindicate corticosteroid use Has any chronic medical condition requiring corticosteroid treatment or has received prior corticosteroid treatment for prostate cancer Has a pathological finding consistent with small cell carcinoma of the prostate Has a known brain metastasis

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01867710

Locations

Belgium
Aalst, Belgium
Brussels, Belgium
Gent, Belgium
Hasselt, Belgium
Kortrijk, Belgium
Leuven, Belgium

Germany
Hannover, Germany
Mülheim, Germany
Nürtingen, Germany
Tübingen, Germany

Hungary
Budapest, Hungary
Miskolc, Hungary

United Kingdom
Birmingham, United Kingdom
Glasgow, United Kingdom
London, United Kingdom
Sutton, United Kingdom
Whitchurch, United Kingdom

Sponsors and Collaborators

Janssen Pharmaceutica N.V., Belgium

More Information

Responsible Party:	Janssen Pharmaceutica N.V., Belgium
ClinicalTrials.gov Identifier:	NCT01867710 History of Changes
Other Study ID Numbers:	CR100916 2012-004331-23 212082PCR2023
Study First Received:	May 30, 2013
Results First Received:	April 6, 2016
Last Updated:	October 5, 2016

Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products Germany: Ethics Commission Great Britain: Medicines and Healthcare Products Regulatory Agency Hungary: National Institute for Quality and Organizational Development in Healthcare and Medicines Germany: Federal Institute for Drugs and Medical Devices Great Britain: Research Ethics Committee Hungary: Health Canada

Keywords provided by Janssen Pharmaceutica N.V., Belgium:
Mineralocorticoid Excess ; Chemotherapy-Naïve; Metastatic Castration-Resistant Prostate Cancer; Abiraterone Acetate; Zytiga; Prednisone; dexamethasone

Additional relevant MeSH terms:

Prostatic Neoplasms	Abiraterone Acetate
Hyperaldosteronism	BB 1101
Genital Neoplasms, Male	Mineralocorticoids
Urogenital Neoplasms	Anti-Inflammatory Agents
Neoplasms by Site	Antiemetics
Neoplasms	Autonomic Agents
Genital Diseases, Male	Peripheral Nervous System Agents
Prostatic Diseases	Physiological Effects of Drugs
Adrenocortical Hyperfunction	Gastrointestinal Agents
Adrenal Gland Diseases	Glucocorticoids
Endocrine System Diseases	Hormones
Dexamethasone acetate	Hormones, Hormone Substitutes, and Hormone Antagonists
Dexamethasone	Antineoplastic Agents, Hormonal
Prednisone	Antineoplastic Agents
Dexamethasone 21-phosphate	Protease Inhibitors

ClinicalTrials.gov processed this record on January 14, 2017