A Study of Adding Apalutamide to Radiotherapy and LHRH Agonist in High-Risk Patients With Prostate-Specific Membrane Antigen-Positron Emission Tomography (PSMA-PET) Positive Hormone-Sensitive Prostate Cancer Participants

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Main Information

Primary registry identifying number
LBCTR2020124661

Protocol number
56021927PCR3015

MOH registration number

Study registered at the country of origin
No

Study registered at the country of origin: Specify
Not yet

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency

Primary sponsor
Janssen-Cilag International NV

Primary sponsor: Country of origin
Belgium

Date of registration in primary registry
09/05/2021

Date of registration in national regulatory agency

Public title
A Study of Adding Apalutamide to Radiotherapy and LHRH Agonist in High-Risk Patients With Prostate-Specific Membrane Antigen-Positron Emission Tomography (PSMA-PET) Positive Hormone-Sensitive Prostate Cancer Participants

Acronym
PRIMORDIUM

Scientific title
A Randomized, Controlled, Multicenter, Open-label Study to Investigate the Efficacy and Safety of Adding Apalutamide to Radiotherapy and LHRH Agonist in High-Risk Patients with PSMA-PET-Positive Hormone-Sensitive Prostate Cancer, with an Observational Follow-up of PSMA-PET-Negative Patients

Acronym

Brief summary of the study: English
The main purpose of this study is to determine if the addition of apalutamide to radiotherapy (RT) plus luteinizing hormone-releasing agonist (LHRHa) delays metastatic progression as assessed by prostate-specific membrane antigen-positron emission tomography (PSMA-PET) or death compared with RT plus LHRHa alone.

Brief summary of the study: Arabic
بالإضافة إلى ناهض المطلق للهرمون (RT) الغرض الرئيسي من هذه الدراسة هو تحديد ما إذا كانت إضافة أبالوتاميد إلى العلاج الإشعاعي اللوتيني (LHRHa) يؤخر تقدم النقيلي كما تم تقييمه بواسطة التصوير المقطعي بالإصدار البوزيتروني لمستضد البروستاتا (PSMA-PET) أو الموت مقارنة بـ RT + LHRHa وحده.

Health conditions/problem studied: Specify
Prostatic Neoplasms

Interventions: Specify

* Radiation: Radiotherapy
* Drug: LHRHa
* Drug: Apalutamide

Key inclusion and exclusion criteria: Inclusion criteria

1- Histologically confirmed adenocarcinoma of the prostate
2- Previously treated with radical prostatectomy with lymph node dissection and first postoperative prostate-specific antigen (PSA) measurement of less than (<) 0.1 nanogram/milliliter (ng/mL) between Week 6 and Week 13
3- Be able to swallow whole the study drug tablets or follow the instructions for admixing with apple sauce
4- Prostate-specific membrane antigen-positron emission tomography (PSMA-PET) must be performed at screening: Patients who are PSMA-PET-positive for at least one loco-regional (pelvic) lesion with or without distant (extra-pelvic) lesions at screening, as determined by Blinded Independent Central Review (BICR), will be eligible to be randomized to either arm of the Interventional Cohort. The investigators will be blinded to the location of the PSMA-PET lesions after randomization and patients who are PSMA-PET-negative for any prostate cancer lesions (that is no loco-regional lesion and no distant lesion) at screening, as determined by BICR, will be eligible for inclusion in the Observational Cohort
5- Biochemically recurrent prostate cancer after RP with a high risk of developing metastasis defined as pathological Gleason score greater than or equal to (≥) 8 at diagnosis or time of surgery, OR PSADT less than or equal to (≤) 12 months at the time of screening using at least 3 consecutive values ≥0.1 nanograms per milliliter (ng/mL), from time of BCR, estimated using the Memorial Sloan Kettering Cancer Center online calculator
6- No evidence of metastases on screening CT/MRI of the chest/abdomen/pelvis, Technetium 99m [99mTc] whole-body bone scan. Participants with a single bone lesion on 99mTc whole-body bone scan should have confirmatory imaging by CT or MRI; if the confirmatory scan confirms the bone lesion, the patient should be excluded from the study. Conventional images (99mTc-bone scan and CT/MRI) from the screening will be sent to BICR for confirmation of metastatic disease before randomization
7- Eastern Cooperative Oncology Group Performance Status Grade 0 or 1

Key inclusion and exclusion criteria: Gender

Male

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

1- History of pelvic radiation for malignancy
2- Previous treatment with androgen deprivation therapy (ADT) for prostate cancer
3- Previously treated for biochemical recurrence (BCR) prostate cancer
Prior treatment with a CYP17 inhibitor (example, oral ketoconazole, orteronel, abiraterone acetate, galeterone) or any androgen receptor (AR) antagonist including bicalutamide, flutamide, nilutamide, apalutamide, enzalutamide or darolutamide and any other medications that may lower androgen levels (estrogens, progestins, aminoglutethimide, etc.), including bilateral orchiectomy
4- Known or suspected contraindications or hypersensitivity to apalutamide, Luteinizing Hormone-Releasing Hormone (LHRH) agonist or any of the components of the formulations
5- Prior chemotherapy for prostate cancer

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization
No

IMP has market authorization: Specify

Name of IMP
Apalutamide (JNJ-56021927)

Year of authorization

Month of authorization

Type of IMP
Others

Pharmaceutical class
Antagonist of the androgen receptor (AR)

Therapeutic indication
Recurrent prostate cancer previously treated with radical prostatectomy

Therapeutic benefit
Improve the condition of patients with prostate cancer

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
Samples with DNA**

Biospecimen description
Blood and tissue (archival tumor samples) samples, retention for up to 15 years

Target sample size
20

Actual enrollment target size

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
01/02/2021

Date of study closure: Type
Anticipated

Date of study closure: Date
31/01/2028

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT04557059

Sources of Monetary or Material Support

Name
Janssen-Cilag International NV Belgium

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Rita Rizk	Building S2B, Downtown Katameya, Road 90, 5th settlement, New Cairo, 11835, Cairo	Egypt	+9617176 5042	rita.rizk@iqvia.com	IQVIA
Scientific	Martin Lukac	Futurama Business Park, Sokolovská 651/136A, Praha 8	Czech Republic	+421 948 155 200	mlukac1@ITS.JNJ.com	Janssen Cilag

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Centre Hospitalier du Nord	Dr. Khalil Armache	Urologist (Genito Urinary Surgery)	Approved
American University of Beirut Medical Center	Dr. Muhammad Bulbul	Urologist	Pending
Notre Dame des Secours Hospital	Dr. Raghid Khoury	Urologist	Approved
Saint George University Hospital Medical Center	Dr. Joseph Makdessi	Urologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Centre Hospitalier du Nord	28/10/2020	Mr. Chaybane Makkary	chn@chn.com.lb	009616555230
Notre Dame des Secours Centre Hospitalier Universitaire	29/10/2020	Pere Wissam Khoury	info@chu-nds.org	009619940400
Saint George Hospital University Medical Center	03/12/2020	Dr. Michel Daher	N/A	009611441000

Countries of Recruitment

Name
Austria
Czech Republic
Denmark
Poland
Russian Federation
Spain
Sweden
Turkey
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Prostatic Neoplasms	Prostate (D40.0)	Prostatic Neoplasms, Genital Neoplasms, Male Urogenital Neoplasms, Neoplasms by Site, Neoplasms, Prostatic Diseases

Interventions

Intervention	Description	Keyword
Apalutamide	Participants will receive therapeutic dose of apalutamide 240 mg tablets once daily for 180 Days	Apalutamide
Radiotherapy	Participants will receive radiotherapy (RT) with or without optional stereotactic body radiation therapy (SBRT), which will start within 4 weeks after randomization.	Radiotherapy
LHRHa	Participants will be administered with LHRHa (example, leuprolide, goserelin, triptorelin acetate) as a 3-monthly depot preparation at Day 1 and Day 85 or as a 6-monthly depot preparation at Day 1	LHRHa

Primary Outcomes

Name	Time Points	Measure
Prostate specific Membrane Antigen-Positron Emission Tomography (PSMA-PET) Metastatic Progression-free Survival (ppMPFS)	Up to 7 years	ppMPFS is defined as the appearance of at least 1 new PSMA-PET-positive distant lesion compared with the previous scan as assessed by blinded independent central review (BICR) or death

Key Secondary Outcomes

Name	Time Points	Measure
Time to Prostate-Specific Antigen (PSA) Progression	Up to 7 years	Time to PSA progression is defined as the time from randomization to the date of first documentation of PSA progression. PSA progression is defined as a PSA concentration above the nadir of more than 0.5 nanogram per milliliter (ng/mL), confirmed by repeated measurement at least 3 Weeks later
PSA Response Rate	Up to 7 years	PSA Response Rate is defined as the percentage of participants with a PSA decrease of >= 50% , >=90% or undetectable from baseline
PSA Levels at week 26	Week 26	PSA levels at week 26 will be reported
Time to Loco-Regional Progression by PSMA-PET	Up to 7 years	Time to loco-regional progression by PSMA-PET as assessed by blinded independent central review (BCIR) is defined as the time from randomization to the date of the first occurrence of PSMA-PET loco-regional progression. Criteria for PSMA-PET loco-regional progression: Appearance of at least one new PSMA-PET-positive loco-regional lesion compared with the previous scan
Overall Survival	Up to 7 years	Overall survival is defined as the time from randomization to date of death from any cause.
Prostate Cancer-Specific Survival	Up to 7 years	Prostate cancer-specific survival is defined as the time from randomization to date of death due to prostate cancer.
Number of Participants With Adverse Event (AE) and Serious Adverse Events (SAEs)	Up to 7 years	An AE is any untoward medical occurrence in a clinical study participant administered a medicinal (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the study vaccine. An AE can therefore be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal (investigational or non-investigational) product. An SAE is any AE that results in: death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect and is a suspected transmission of any infectious agent via a medicinal product.

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files