An Open-label Phase 1b QT/QTc Study of JNJ-56021927 (ARN-509) in Subjects With Castration-Resistant Prostate Cancer.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON47113

Source
ToetsingOnline

Brief title
QT/QTc Study of JNJ-56021927 (ARN-509) in Subjects With Prostate Cancer.

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson Pharmaceutical
Source(s) of monetary or material Support: Janssen Research and Development

Intervention

Keyword: JNJ-56021927, Prostate cancer patients, QT/QTc study

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the effects of JNJ-56021927 and its active metabolite JNJ-56142060 on ventricular repolarization (QTcF) by using time-matched ECGs at baseline and on study drug.

Secondary outcome

- To evaluate the effect of JNJ-56021927 on other ECG parameters (HR, QT interval, Bazett*s QT correction [QTcB] interval, QT interval using study-specific Power [QTcP], RR interval, PR interval, QRS interval, T-wave morphology, and U-wave morphology).

- To evaluate the pharmacokinetics of JNJ-56021927 and its active metabolite, JNJ-56142060.

- To determine the potential relationship between the plasma concentrations of JNJ-56021927, JNJ-56142060, and QTcF.

- To evaluate the safety of JNJ-56021927.

Study description

Background summary

At present, there is no cure for advanced prostate cancer. IThe goal is to develop a treatment that will allow men with prostate cancer to live longer lives and to slow down the potential for prostate cancer spreading in the body. Assessing the cardiovascular safety of novel cancer compounds is now a global regulatory prerequisite for marketing approval.

Study objective

The purpose of this study is to evaluate the effect of a single dose of JNJ-56021927 on the heart*s electrical activity and to see how the body processes the study drug in subjects with Castration-Resistant Prostate Cancer. Further the safety of JNJ-56021927 is investigated

Study design

This is a multicenter, Phase 1b open-label study to investigate the effect of a single dose of JNJ-56021927 on the electrical activity of the heart.
All patients in this study receive the same treatment.
Treatment is continued as long as the cancer is responding well to the treatment and as long as the study drug is well tolerated.

Intervention

The study will consist of a 28-day screening, a treatment and a follow-up phase.

During the screening the investigator determines whether the patient is eligible to participate in the study.

During treatment, the patient will receive 240 mg JNJ-56021927 once daily in cycles of 28 days.
On Day -1 (1 day prior to the first dose), Day 1 and Day 57 (Day 1 of cycle 3) ECGs will be made up to 5 hours post-dose (Day -1 for the scheduled dosing time of the dose on Day 1).
On Day 1 and Day 57, PK samples will be collected up to five hours after dosing.

All subjects will continue on study until disease progression, withdrawal of consent, lost to follow-up, or the occurrence of unacceptable toxicity.
Upon discontinuation from study drug, subjects will return for an EoT visit no longer than 30 days after their last dose.

Study burden and risks

This is described in the patient information as follows:

The possible discomforts, side effects, and risks related to JNJ-56021927, also known as ARN 509, treatment are not all known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. You will be watched carefully during this study for any side effects.
Sometimes during a study the Sponsor or study doctor may learn new facts about the study medications. It is possible that this information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it.

Side effects may be mild or serious. All medicines have the potential to cause an allergic reaction. Some allergic reactions and side-effects may potentially be life threatening. If you do experience any side effects, your doctor may need to give you medicines to help lessen the side effect. Many side effects may go away soon after you stop taking the study medicine. In some cases, side effects can be serious or long lasting.

If you experience a side effect, your treating doctor may change your study drug doses in an effort to decrease or stop any side effects. If severe side effects do develop, you and your doctor may decide that it is in your best interest to stop taking part in the study. If you choose, you always have the right to withdraw from the study. In addition, you will be provided with the telephone numbers for people, who can answer any questions about the study, your rights as a study participant and for you to report any side effects.

Risks and side effects that may be possibly related to ARN-509 include:
Very Common (>10%): Fatigue, Skin rash, Joint pain (arthralgia), weight loss, fall, fractures
Common (1-10%): Itching, hypothyroidism, increase in blood cholesterol, increase in triglycerides.
Very Rare (<1%): seizure

Side effects from tests:
* Bood draw: Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.
* EG Risk (including holter monitoring): There is generally no risk with having an ECG or holter monitoring. The sticky patches may pull your skin or cause redness or itching.
* Rsks from the MUGA Scan and Radioactive Tracer: Procedures such as CT scans, X-rays and/or radioactive drugs will be used during this research study to see how you are doing. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you or your disease. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.
* Risk from the echocardiogram: there is generally no risk with having an echocardiogram. It is a non-invasive procedure using ultrasound waves. There are no known risks from the ultrasound waves. The echocardiogram is also painless, although you may feel slight discomfort when the transducer is held firmly against the chest.

Contacts

Public
Johnson & Johnson Pharmaceutical

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1;- Adenocarcinoma of the prostate; either non-metastatic castrate resistant prostate cancer (NM-CRPC) with high risk disease (defined as PSA Doubling time equal or less than (*) 10 months) or metastatic CRPC;- Be surgically or medically castrated with testosterone levels of <50 ng/dL;- If treated with a gonadotropin releasing hormone analog (ie, patient who has not undergone bilateral orchiectomy), then this therapy must have been initiated at least 4 weeks prior to Cycle 1 Day 1 and must be continued throughout the study;- Electrocardiogram (ECG) showing a QT interval corrected for heart rate, using Fridericia formula (QTcF) * 470 msec (based on the average of a triplicate ECG set collected during the screening visit;- Left ventricular ejection fraction (LVEF) of >45% as determined by multiple uptake gated acquisition (MUGA) or chocardiography at the screening visit

Exclusion criteria

- Abnormal cardiac function at screening;- Known brain metastases;- Has received an investigational drug within 4 weeks, or within a period less than 10 times the drug*s half-life, whichever is longer, of Cycle 1 Day 1;- Has received chemotherapy or immunotherapy for the treatment of prostate cancer within 4 weeks of Cycle 1 Day 1;- Use of therapies that must be discontinued or substituted within at least 4 weeks priorto Cycle 1 Day 1 including medications to lower seizure threshold, inducing/inhibiting metabolizing enzymes or prolonging the QT interval;- History or condition that may predispose to seizures, or evidence of severe or unstable angina, myocardial infarction, symptomatic congestive heart failure, arterial or venous thromboembolic events within 12 months prior to Cycle 1 Day 1, New York Heart Association (NYHA) Class II to IV heart disease

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.V.T
Generic name:	JNJ-56021927

Ethics review

Approved WMO Date:	11-11-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-10-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-11-2017
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	07-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-06-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	12-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-05-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-004044-19-NL
CCMO	NL55264.078.15