IVD1: Clinical Performance Study Plan For The Use of Myriad MyChoice® For Patient Enrolment Into the AZD5305 (Saruparib) vs Placebo in Participants with Metastatic Castration-Sensitive Prostate Cancer Receiving Physician*s Choice New Hormonal Agents;IVD2: Clinical Performance Study Plan for F1LCDx Used in Clinical Trial EvoPAR-Prostate01 ;Main: A Randomized, 2-cohort, Double-blind, Placebo-controlled, Phase III Study of AZD5305 in Combination with Physician*s Choice New Hormonal Agents in Patien

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IVD1: The primary objective of this clinical performance study is to evaluate the effectiveness of the MyChoice® test in identifying HRRm or non-HRRm mCSPC patients as part of the enrolment criteria for EvoPAR-prostate01. This clinical performance...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON56674

Source
ToetsingOnline

Brief title
EvoPAR-Prostate01

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Metastatic Castration-Sensitive Prostate Cancer, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: AstraZeneca

Intervention

Keyword: Castration-sensitive prostate cancer, F1LCDx, Myriad MyChoice®

Outcome measures

Primary outcome

IVD1: The clinical performance is defined as the ability of the device to act as a companion diagnostic in mCSPC patients for treatment eligibility with AZD5305 (Saruparib) plus SOC ADT + NHA. The primary endpoint of the main study is to demonstrate superiority of AZD5305 (Saruparib) + physician*s choice NHA relative to placebo + physician*s choice NHA by assessment of radiographic progression-free survival (rPFS) in participants with mCSPC (in BRCAm and in non-HRRm).

IVD2: The clinical performance is defined as the ability of the device to act as a companion diagnostic in mCSPC patients for treatment eligibility with AZD5305 (saruparib) plus SOC ADT + NHA. The primary endpoint of the main study is to demonstrate superiority of AZD5305 (saruparib) + physician*s choice NHA relative to placebo + physician*s choice NHA by assessment of radiographic progression-free survival (rPFS) in participants with mCSPC (in BRCAm and in non-HRRm).

Secondary outcome

N/A

Study description

Background summary

IVD1: This clinical performance study will utilize the Myriad MyChoice test to prospectively select patients for further stratification and subsequent randomization into the EvoPAR-prostate01 (D9723C0001) study, which is a double-blind, Phase III study of AZD5305 (Saruparib) in combination with physician*s choice new hormonal agents in patients with HRRm and non-HRRm metastatic Castration-Sensitive Prostate Cancer. As such, use of the device will be restricted to [pre-screening or screening] and will occur prior to the receipt of any investigational therapy(ies). This stratification study will prospectively test tumour FFPE using the MyChoice test to identify patients with either HRRm or non-HRRm for the treatment with AZD5305 (Saruparib) plus ADT/NHA, or placebo plus ADT/NHA.

The EvoPAR-prostate01 study will study the efficacy and safety of AZD5305 (Saruparib) plus ADT/NHA compared with placebo plus ADT/NHA in patients with mCSPC in HRRm and non-HRRm populations separately.
The efficacy analyses conducted by AstraZeneca for EvoPar Prostate 01 to evaluate the efficacy and safety of their investigational therapy will also provide the basis for the clinical performance evaluation of the MyChoice to identify HRRm or non HRRm patients who will benefit from AZD5305 (Saruparib) in combination with new hormonal agents.

IVD2: This clinical performance study protocol (CPSP) relates to the use of the

FoundationOne®Liquid CDx (F1LCDx) assay as part of the EvoPAR-prostate01 drug clinical study to identify HRRm or non-HRRm metastatic Castration-Sensitive Prostate Cancer (mCSPC) patients. Whilst the clinical performance study and corresponding CPSP will comply with relevant requirements under the IVDR (Regulation (EU) 2017/746), the clinical study for the investigational medicinal product (IMP) will comply with relevant requirements under the clinical trials regulation (CTR; Regulation (EU) No 536/2014; link). This document relates solely to IVDR requirements, and the diagnostic device used for patient selection, unless otherwise specified.

The objective of this clinical performance study is to establish the clinical performance of the F1LCDx assay as a companion diagnostic (CDx) for AZD5305 (saruparib, PARPi) in patients with mCSPC harbouring qualifying alterations in HRR genes, specifically ATM, BARD1, BRCA1, BRCA2, CDK12, PALB2, RAD51B, RAD51C, or RAD51D. This clinical performance study will be conducted in accordance with the EU Regulation 2017/746 on in vitro Diagnostic Medical Devices and ISO 20916:2019 In vitro diagnostic medical devices * Clinical performance studies using specimens from human subjects * Good study practice, and to provide data to demonstrate the product is safe and effective for its intended use.

This clinical performance study plan (CPSP) will be executed in combination with the clinical trial, EvoPAR-Prostate01(D9723C00001). D9723C00001 is a Randomized, 2-cohort, Double-blind, Placebo-controlled, Phase III Study of AZD5305 (saruparib) in Combination with Physician*s Choice New Hormonal Agents in Patients with HRRm and non-HRRm mCSPC.

Study objective

IVD1: The primary objective of this clinical performance study is to evaluate the effectiveness of the MyChoice® test in identifying HRRm or non-HRRm mCSPC patients as part of the enrolment criteria for EvoPAR-prostate01. This clinical performance study is intended to obtain clinical evidence for use of this device as a CDx in mCSPC patients for treatment eligibility with AZD5305 (Saruparib) plus ADT/NHA. This clinical performance study is to support the AZ EvoPAR-prostate01 clinical trial (D9723C00001) by determining HRR gene mutation status in FFPE tumour samples from mCSPC subjects as part of enrolling patients in AZ EvoPAR-prostate01 clinical trial (D9723C00001).

IVD2: This clinical performance study will evaluate the effectiveness of the F1LCDx test in identifying HRR status in metastatic castration sensitive prostate cancer patients and generate clinical validation data for the diagnostic device.

This clinical performance study is to support the AZ EvoPAR-Prostate01 clinical trial (D9723C00001) by determining HRR gene mutation status in ctDNA from mCSPC subjects as part of enrolling patients in AZ EvoPAR-Prostate01 clinical trial

(D9723C00001).

Study design

Myriad MyChoice® and F1LCDx assay will be used to assess the HRRm expression from tumor specimens and blood (ctDNA) collected from patients who are being screened to determine eligibilty to participate in AstraZeneca study EvoPAR-Prostate01.

IVD1: Myriad MyChoice® is a qualitative, semi-automated next generation sequencing-based in vitro diagnostic test to detect and classify single nucleotide variants, insertions and deletions, and large rearrangements in a multi-gene panel and to calculate the genomic instability score (GIS) using DNA isolated from fixed tumor tissue specimens. The test is intended to be used as a companion diagnostic to select patients with specific cancer types for treatment with targeted therapy as listed in the table below.

IVD2: F1LCDx utilizes ctDNA isolated from plasma derived from the anti-coagulated peripheral whole blood of cancer patients. The test is intended to be used as a CDx to identify patients who may benefit from treatment with targeted therapies in accordance with the approved therapeutic product labeling. Additionally, F1LCDx is intended to provide tumour mutation profiling for patients with malignant neoplasms.

Intervention

Blood sample will be collected during the HRRm biomarker period. If not present: tumor biopsy is collected as well.

Study burden and risks

A blood sample is taken during the biomarker testing period and a new biopsy may have to be taken if no or not enough tissue is available.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

IVD1:
- Provision of a FFPE tumour tissue sample and a blood sample (for ctDNA) as specified.
- FFPE samples from primary or metastatic sites.
- Archival or newly acquired FFPE tumour tissue samples are permitted provided they are taken as part of routine clinical practice.
- Specimens must be either a solid tumour prepared as an FFPE block or FFPE slide sections that are 4-5 microns thick.

IVD2:
- 2 x 10mL Streck Cell-Free DNA BCT collection tubes of whole blood must be submitted prior to study enrollment for testing with F1LCDx.
- Samples to be provided prior to starting ADT, if possible.
- To ship as soon as possible after collection within the 14 days stability window at temperature range of 6°C to 37°C.

Exclusion criteria

IVD1:
- Tumour Content (<20%)*.
- Number of slides (<21)*.
- Stained or broken slides.
- Bone metastasis samples with acid decalcification treatment, brain metastasis

and central nervous system metastasis.
- Specimen taken from previously irradiated lesion.
* if a sample does fall below these levels, the site should contact the AstraZeneca study team for advice before excluding the sample.

IVD2:
- Tissue, other liquid samples besides whole blood are excluded.
- Samples yielding plasma volume <2.5mL.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2024
Enrollment:	19
Type:	Actual

Medical products/devices used

Generic name:	IVD1: Myriad MyChoice assay / IVD2: F1LCDx assay
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	27-03-2024
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL85496.000.23