An open-label, single arm, roll-over study to provide continued treatment with darolutamide in participants who were enrolled in previous Bayer-sponsored studies

Published: 24-08-2021
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This study has been transitioned to CTIS with ID 2022-502084-38-00 check the CTIS register for the current data. Primary- Continuation of treatment- SafetySecondairy- Documentation of tolerability

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

Summary

ID

NL-OMON52006

Source
ToetsingOnline

Brief title
Darolutamide roll-over study

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
hormone-sensitive, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer Consumer Care AG

Intervention

Keyword: Darolutamide, Roll-Over study, ROS

Outcome measures

Primary outcome

- Incidence of Treatment-emergent adverse events (TEAEs)

- Incidence of Treatment-emergent serious adverse events (TESAEs)

- Incidence of drug-related TEAEs and TESAEs

Secondary outcome

- Frequency of dose modifications

Study description

Background summary

Darolutamide works as an androgen receptor inhibitor. In a prostate cancer cell, the androgen (male hormone) *testosterone* connects with the androgen receptor, which may cause the growth of the tumor cell. Darolutamide helps to prevent the attachment of testosterone to the androgen receptor and thus prevents prostate tumor growth.

The study drug will be given in conjunction with the current hormonal treatment, as known by the patient.

Study objective

This study has been transitioned to CTIS with ID 2022-502084-38-00 check the CTIS register for the current data.

Primary
- Continuation of treatment
- Safety

Secondairy
- Documentation of tolerability

Study design

This is an open-label, single-arm roll-over study (ROS) to enable participants receiving darolutamide in any Bayer-sponsored feeder study, to continue receiving darolutamide treatment beyond the feeder study primary completion or closure.

Intervention

Darolutamide
Twice daily 600 mg (2 x 300 mg tablets), total daily dose 1200 mg
Orally taken with food
In addition to standard of care.

Study burden and risks

The investigator of the feeder study is expected to assess the overall benefit/risk for each participant. When the study investigator deems there is a positive benefit/risk assessment and no treatment withdrawal criteria of the feeder study have been met, the participant can continue to receive treatment in this roll-over study.

Contacts

Public
Bayer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol
2. Participants enrolled in any Bayer-sponsored darolutamide feeder study at the time of study closure or primary completion, who are currently receiving darolutamide and are experiencing clinical benefit from treatment.
3. Participants who have not met any treatment discontinuation criteria outlined in the feeder study protocol.
4. Willingness to continue practicing acceptable methods of birth control during the study.

Exclusion criteria

1. Participant is unable to comply with the requirements of the study.
2. Negative benefit/ risk ratio as determined by the investigator.
3. Meet any criteria for treatment discontinuation of the feeder study the participant is coming from.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-02-2022
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	darolutamide
Generic name:	Nubeqa
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-08-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	01-12-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	10-03-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	01-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	07-04-2022

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	02-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	05-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	11-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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
EU-CTR	CTIS2022-502084-38-00
EudraCT	EUCTR2019-003618-15-NL
ClinicalTrials.gov	NCT04464226
CCMO	NL78045.058.21