Machine learning prediction of anemia events before and after talazoparib dose modification using TALAPRO-2 phase 3 trial data

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000344

EU PAS number

EUPAS1000000344

Study ID

1000000344

DARWIN EU® study

No

Study countries

☐ United States

Study description

The risk of anemia due to talazoparib is common and may be a barrier in its utilization and/or lead to premature treatment discontinuation. Successful prediction of this adverse event in patients receiving talazoparib is an important step in understanding and reducing the risk of such toxicities while maintaining patients on treatment through individualized patient-centered approaches such as more vigilant monitoring and early dose management. The primary goal of this study is to assess how well machine learning models predict anemia events before and after talazoparib dose modification. The objectives are: 1. Describe patient characteristics, dosing patterns and hemoglobin trajectories with respect to anemia events in talazoparib-treated metastatic castrate-resistant prostate cancer (mCRPC) patients from the TALAPRO-2 trial data; 2. Develop and evaluate machine learning prediction models of anemia risk after treatment initiation and preceding dose modification; 3. Develop and evaluate machine learning prediction models of anemia recovery after dose modification. This is a non-interventional (NI), observational, retrospective study with secondary data analysis of already existing clinical trial data. This study will use the existing TALAPRO-2 trial data of mCRPC patients allocated to the talazoparib + enzalutamide treatment arm and included in the safety analysis. A variety of machine learning models including LASSO Cox regression, extreme gradient boosting, survival support vector machine, and deep cox proportional hazards model will be applied to identify the best performing model for predicting anemia risk and recovery based on performance metrics such as concordance index (test c-index) and dynamic area under the curves (AUCs).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 30/09/2024

Study start date
Planned: 11/11/2024

Actual: 02/12/2024

Date of final study report
Planned: 14/02/2026

Study protocol

C3441068 NI study protocol anemia ML prediction 20241025_clean.pdf(639.72 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study drug and medical condition

Name of medicine

TALZENNA

Study drug International non-proprietary name (INN) or common name

TALAZOPARIB

Anatomical Therapeutic Chemical (ATC) code

(L01XK04) talazoparib

talazoparib

Data management

Data sources

Data sources (types)

Clinical trial

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No