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

First published: 19/11/2024

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Study Ongoing

Administrative details

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

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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

Data analysis start date
Actual: 22/08/2024

Date of final study report
Planned: 30/06/2026

Study protocol

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

C3441068_Protocol_V2_12 June 2025_Redacted.pdf (267.14 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Method development or testing

Data collection methods:

Secondary use of data

Study design:

NI, observational, retrospective cohort study of mCRPC patients who received talazoparib in the treatment arm

Main study objective:

Primary objectives:

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.

Exploratory objective:

1. Describe patient characteristics and hemoglobin trajectories with respect to anemia events in control-arm mCRPC patients from the TALAPRO-2 trial data

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TALZENNA

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

TALAZOPARIB

Anatomical Therapeutic Chemical (ATC) code

(L01XK04) talazoparib

talazoparib

Medical condition to be studied

Anaemia

Population studied

Short description of the study population

TALAPRO-2 trial data of metastatic castrate-resistant prostate cancer (mCRPC) patients allocated to the talazoparib + enzalutamide

Study design details

Data analysis plan

For Primary Objective 1, descriptive statistics will be used to summarize baseline patient characteristics (demographic, clinical, treatment history, lab

values) overall and stratified by subsequent anemia status; to summarize early dose patterns with respect to initial post-index anemia status and dose modification; to summarize baseline patient characteristics and subsequent anemia status by early dose pattern strata; to summarize the proportion of patients who improved, remained the same, or worsened in anemia severity following dose modification; and to summarize the rate of hemoglobin change prior to and after dose modification. Time to dose modification, time to anemia, and time to anemia improvement will be assessed using Kaplan-Meier survival analyses. For Objectives 2 and 3, 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). Exploratory objective 1 will be assessed similarly as Objective 1, with descriptive statistics to be used to summarize baseline patient characteristics (demographic, clinical, treatment history, lab values) overall and stratified by subsequent anemia status; and to summarize the rate of hemoglobin change after study initiation. Time to anemia will be assessed using Kaplan-Meier survival analyses. No dose modification-related concepts will be assessed for exploratory objective 1 since dosing is not applicable for the control arm.

Documents

Study report

C3441068 Study Report_Redacted.pdf (2.52 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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