Multimodal response prediction to the 177Lu-PSMA radioligand therapy with metastatic prostate cancer

First published: 09/01/2023

Last updated: 09/01/2023

Study Planned

Administrative details

EU PAS number

EUPAS50368

Study ID

50369

DARWIN EU® study

No

Study countries

Austria

Study description

The objective of the trial is to investigate the predictability of the therapy response to the 177Lu-PSMA radioligand therapy in men with metastatic prostate cancer using data from routinely acquired functional positron-emission tomography/computed tomography, clinical parameters and cell-free DNA derived from blood samples.

Study status

Planned

Research institutions and networks

Institutions

Medical University of Vienna

Austria

First published: 01/02/2024

Last updated: 26/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

Kilian Kluge kilian.kluge@meduniwien.ac.at

Study contact

kilian.kluge@meduniwien.ac.at

Primary lead investigator

Alexander Haug

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/04/2018

Study start date
Planned: 01/02/2023

Date of final study report
Planned: 01/01/2025

Sources of funding

- Other

More details on funding

Christian Doppler Society

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Non-invasive response biomarker study

Main study objective:

Prediction of response to the 177Lu-PSMA I&T therapy based on cell-tumor DNA derived from blood samples as well as routine clinical and imaging data

Study drug and medical condition

Medical condition to be studied

Prostate cancer metastatic

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

60

Study design details

Outcomes

prostate-specific antigen decline >50 %, progression-free survival (PFS)

Data analysis plan

identification of prognostic compound (radiologic + genetic + epigenetic) biomarkers

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)

Other

Data sources (types), other

Prospective patient-based data collection

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