A Non-Interventional Post-Authorization Safety Study (NI-PASS) as an effectiveness check of a Patient Card for Padcev™

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Study Finalised

Administrative details

EU PAS number

EUPAS104456

Study ID

104457

DARWIN EU® study

No

Study countries

France

Germany

Italy

Poland

Spain

Sweden

Switzerland

Study description

Padcev is a treatment for cancer in the bladder lining (urothelial cancer). Padcev is injected through a vein (known as an infusion). Padcev is now available in some countries in Europe.

People in this study will be adults with locally advanced (the cancer has spread to nearby tissue) or metastatic urothelial cancer. Metastatic means the cancer has spread to other parts of the body.

During their care, the person’s doctor will have prescribed Padcev treatment and other medicines to treat their cancer.

People in the study will be treated according to their clinic’s standard practice. This study is about collecting information only.

This study will survey people who know they are receiving Padcev treatment and have been given an information leaflet called a Patient Card.

The aim of the study is to check how well people understand the information on the Patient Card, including the risk of skin reactions that can be caused by Padcev treatment. Once a doctor has prescribed Padcev treatment, the patient (or their caregiver) will be asked if they would like to complete a survey. The survey will be completed on a computer and should take about 15 minutes to complete.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Samantha Kimball

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2023

Actual: 21/09/2022

Study start date

Planned: 02/01/2024

Actual: 27/03/2024

Data analysis start date

Planned: 07/05/2025

Actual: 02/04/2025

Date of final study report

Planned: 29/07/2025

Actual: 12/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas

Study protocol

7465-PV-0002_Padcev_NI-PASS_Protocol_v3_Oct2024-redacted.pdf (1.02 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

7465-PV-0002

Methodological aspects

Study type

Study type list

Study topic:

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

This is a multi-national, non-interventional, cross-sectional survey study with primary data collection to evaluate the effectiveness of patient education materials for Padcev™ (the Padcev™ PC).

Main study objective:

The objectives of this NI-PASS are to assess patients' (or caregivers') knowledge of the risk of skin reactions associated with the use of Padcev™, as well as awareness of the Padcev™ Patient Card (PC), knowledge of the content of the PC, and reported behaviors to minimise the risk of skin reaction.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

PADCEV

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

ENFORTUMAB VEDOTIN

Anatomical Therapeutic Chemical (ATC) code

(L01FX13) enfortumab vedotin

enfortumab vedotin

Population studied

Short description of the study population

The study population will be patients in 7 European countries (France, Germany, Italy, Poland, Spain, Sweden, and Switzerland) with locally advanced or metastatic urothelial carcinoma who previously received platinum and PD-1/L1 inhibitor therapy and have received or are currently receiving Padcev™ therapy. If a patient is unable to participate in the survey, their caregiver will be asked to participate.

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

62

Study design details

Outcomes

- Knowledge levels of patients, or their caregivers, of the risk of skin reactions associated with the use of Padcev™,
- Knowledge of the symptoms and recommended care for skin reactions associated with the use of Padcev™
- Knowledge levels of patients, or their caregivers, of the symptoms and recommended care for skin reactions associated with the use of Padcev™
- Reported behaviors of patients, or their caregivers, to minimise the risk associated with the use of Padcev™.

Data analysis plan

A statistical analysis plan will be developed to describe all planned analyses in detail, along with shells for variable lists, tables and figures.
All analyses will be performed using SAS® V9.0 or later.
A final report summarizing the results of the survey will be developed.
The study population included in the data analysis will include patients/caregivers who completed the question in the survey associated with the primary endpoint.
A threshold of success for the primary endpoints is to have 80% or more patients/caregivers providing a correct response to this question. Descriptive data analyses will be conducted. Levels of awareness and knowledge, self-reported behaviors as well as patient characteristics will be calculated with 95% two-sided Confidence Intervals. Descriptive results will be reported for the overall population of respondents and by country and, if the data permit, for sub-groups such as patients versus caregivers or length of time receiving Padcev™ treatment.

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

Patient surveys

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