A Prospective, Non-interventional, Observational Post-authorisation Study to Assess the Late-effects of Patients who have received Unituxin (ALIVIO)

First published: 22/07/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14095

Study ID

17796

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

☐ Netherlands

☐ Norway

☐ Spain

☐ United Kingdom

Study description

Following assessment of the global availability of Unituxin, UTC has decided to terminate the trial due to significant short and intermediate-term drug supply shortages. The study has been terminated on 15 December 2016. Please also note, no data was collected as per section 3, only planned dates have been populated in the actual dates field due to restrictions on the form.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

☐ Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Alessandra Pranzo druginformationUTEL@unither.com

Study contact

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Primary lead investigator

Janine Collins

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/04/2016

Study start date

Planned: 02/01/2017

Actual: 15/12/2016

Date of final study report

Planned: 11/03/2030

Actual: 15/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

United Therapeutics Corporation (UTC)

Study protocol

DIV-NB-402 Final Protocol Version 2.0_16Aug2016.pdf(4.06 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the late-effects associated with the central and peripheral nervous system, growth and endocrine development, auditory, visual, hepatic, renal, lower urinary tract, cardiac, respiratory, skeletal, second and secondary malignancies in patients who received Unituxin for neuroblastoma and remain event-free for at least 5 years since the start of Unituxin immunotherapy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational cohort registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC16) dinutuximab beta

dinutuximab beta

Medical condition to be studied

Neuroblastoma

Population studied

Short description of the study population

High-risk neuroblastoma patient for whom a decision has been made to commence Unituxin immunotherapy.
Patients who are participating in study DIV-NB-401, a Post-marketing Study to Further Assess the Immunogenicity and Safety of Unituxin in High-Risk Neuroblastoma Patients werel also eligible to participate in this study.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Neuroblastoma patients

Estimated number of subjects

590

Study design details

Outcomes

The late effects associated with the relevant systems and second/secondary malignancies will be analysed in the Safety Set of patients by comparing the characteristics at 12 months to 5 years tothe characteristics at baseline using descriptive statistics. Event-free survival (EFS) and Overall Survival (OS) will be assessed every 6 months for up to 5 years following treatment. EFS will be calculated as the time from start of Unituxin until the first occurrence of the events of relapse, PD, secondary malignancy, or death. If no event occurs, the date of last contact will be used. OS will be calculated as the time from start Unituxin until death.

Data analysis plan

All analyses will be performed using SAS for Windows statistical software using validated implementations of each application or SAS custom programming. The data from all centres will be combined, so that an adequate number of patients will be available for analyses. Summary tabulations will be presented that will display the number ofobservations, mean, standard deviation, median, minimum and maximum for continuous variables, and the number and percentage per category for categorical or ordered categorical data. In addition, two sided 95% confidence intervals will be calculated for all outcomes when possible.

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, Case report forms will be designed to gather data from the medical records

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

Unknown