Proton therapy for head and neck cancer therapy: A real-world data case study from Bulgaria

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000569

EU PAS number

EUPAS1000000569

Study ID

1000000569

DARWIN EU® study

No

Study countries

☐ Bulgaria

Study description

Real-World Data Analysis of Proton Therapy for Head and Neck Cancer Using Danny Platform

Study status

Finalised

Research institutions and networks

Institutions

Faculty of Pharmacy, Medical University - Sofia, Bulgaria

Contact details

Study institution contact

Daniel Penchev

Study contact

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Primary lead investigator

Maria Dimitrova

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/05/2023

Actual: 17/05/2023

Study start date
Planned: 01/01/2020

Actual: 01/01/2020

Date of final study report
Planned: 02/07/2024

Actual: 02/07/2024

Sources of funding

- No external funding

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

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

Data collection methods:

Secondary use of data

Study design:

To assess the access to proton therapy for head and neck cancer (HNC) patients using RWD analyzed by Sqilline’s Danny Platform.

Main study objective:

To evaluate the feasibility of establishing a national proton therapy center in Bulgaria.

To analyse strategic policy documents to understand the level of support and potential challenges for implementing proton therapy in Bulgaria.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Head and neck cancer

Population studied

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Outcomes

From 2020 to 2022, only ten children with head and neck cancer were referred abroad for proton therapy, underscoring the lack of local facilities. These

patients, with an average age of 9.8 years, received treatment in Germany, Italy, Austria, and Russia.

Documents

Study publications

Proton therapy for head and neck cancer therapy: A real-world data case study f...

Data management

Data sources

Data source(s)

Danny Platform

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable