

# A long-term non-interventional study to assess the incidence of skin malignancies in patients with dystrophic and junctional epidermolysis bullosa receiving treatment with Filsuvez (FOSTER)

**First published:** 05/07/2024

**Last updated:** 02/07/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000244

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### Study ID

1000000244


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### DARWIN EU® study

No

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### Study countries


 Austria

 France


 Germany

 Greece

 Italy

 Netherlands

 Spain

 United Kingdom

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## Study description

In patients with epidermolysis bullosa (EB), collagen does not form properly, so their skin is very fragile and blisters easily. Such patients are also at greatly increased risk of developing skin cancers. Filsuvez is a topical gel used to promote healing of skin lesions in patients with certain types of EB. In this observational study, patients with either dystrophic EB (DEB) or junctional EB (JEB) will receive standard of care treatment, whether Filsuvez or something else, and will be followed for up to 5 years. The main purpose is to see if the use of Filsuvez affects the likelihood of developing skin malignancies in these patient populations.

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## Study status

Planned

# Research institutions and networks

## Institutions

**Amryt Pharmaceuticals DAC**

 Ireland

**First published:** 20/03/2024

Last updated: 20/03/2024

Institution

Pharmaceutical company

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Jemima Mellerio

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/10/2024

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### Study start date

Planned: 01/11/2024

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### Data analysis start date

Planned: 01/07/2026

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### Date of interim report, if expected

Planned: 01/11/2026

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### **Date of final study report**

Planned: 01/12/2032

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

[ed-amryt-iab23965protocolpassv30 \(1\).pdf](#) (1.26 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

NCT06423573

[Link to Clinicaltrials.gov](#)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

Post-authorization safety study (PASS) with a non-interventional cohort design, based on primary data collection from patients enrolled at participating dermatology sites and secondary use of registry data from patients included in EB registries.

**Main study objective:**

To estimate the incidence of first skin malignancy during follow-up in patients exposed to Filsuvez.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

FILSUVEZ

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**Medicinal product name, other**

Oleogel-S10

Birch bark extract

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**Anatomical Therapeutic Chemical (ATC) code**

(D03AX13) Betulae cortex

Betulae cortex

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**Medical condition to be studied**

Epidermolysis bullosa

## Population studied

**Short description of the study population**

Patients with either dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) who are considered at risk for developing skin malignancies.

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**Age groups****• Paediatric Population (< 18 years)**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- 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 ( $\geq$  65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
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## **Estimated number of subjects**

580

## **Study design details**

### **Setting**

Patients who are receiving standard of care from their physician or who are enrolled in EB registries will be followed for the occurrence of skin malignancies from the date of study enrollment to the date of discontinuation or end of the study. Follow-up will be for approximately 5 years.

Patients with a confirmed diagnosis of either DEB or JEB are eligible. There are no exclusion criteria. The incidence of skin malignancies will be assessed both in patients receiving Filsuvez and those not receiving it.

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### **Comparators**

Patients will receive whatever treatment their doctor is prescribing for them, whether Filsuvez or something else. Out of the planned total of 580 patients, it is expected that approximately half will be using Filsuvez.

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### **Outcomes**

The primary outcome measure is incidence of first skin malignancy during follow-up in EB patients receiving Filsuvez. Patients will be followed for the occurrence of skin malignancies from the date of study enrolment until either the date of discontinuation or termination of the study. The main secondary outcome measures is the incidence of first skin malignancy during follow-up in EB patients not receiving Filsuvez over this same time period.

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### **Data analysis plan**

This study is purely descriptive, and will not include any statistical testing of outcomes between Filsuvez-exposed and unexposed patients. Demographic, clinical characteristics, Filsuvez use patterns, and characteristics of skin malignancies will be included in the descriptive analyses of the Filsuvez-exposed and unexposed patients. Continuous variables will be described using mean, standard deviation, median, first and third quartiles, interquartile range, range, as appropriate. Categorical variables will be described with counts and percentages (relative to the number of non-missing observations for each variable).

## 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 source(s), other**

Primary data sources: Participating dermatology clinics

Secondary data sources: EB registries

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### **Data sources (types)**

[Disease registry](#)

[Non-interventional study](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

No