A Study to Evaluate the Vaccine Effectiveness of Abrysvo® for Preventing RSV Hospitalizations in Adults Aged 60 Years or Above (Complementary Study to DAN-RSV)

First published: 04/06/2025

Last updated: 02/07/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000480

Study ID

1000000480

DARWIN EU® study

No

Study countries

Denmark

Spain

Study description

The primary objective is to evaluate Abrysvo® vaccine effectiveness (VE) against hospitalization for RSV-related or all-cause respiratory and cardiopulmonary outcomes in adults stratified by immunocompromised status.

Study status

Ongoing

Research institutions and networks

Institutions

Copenhagen University Hospital – Herlev and Gentofte

Contact details

Study institution contact

Sine Hojlund Christensen

sine.hojlund.christensen@regionh.dk

Study contact

sine.hojlund.christensen@regionh.dk

Primary lead investigator

Tor Biering-Sorenson

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/05/2025

Study start date
Planned: 31/05/2025

Actual: 03/07/2025

Data analysis start date
Planned: 31/05/2025

Actual: 03/07/2025

Date of final study report
Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

C3671080

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study topic, other:

Vaccine Effectiveness

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ABRYSVO

Medicinal product name, other

Bivalent respiratory syncytial virus (RSV) prefusion F subunit vaccine

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Respiratory syncytial virus infection

Hospitalisation

Population studied

Short description of the study population

The study population will include adults aged 18 years of age and older in Denmark and Galicia, Spain

Age groups

- Adults (18 to < 65 years)
- Elderly (≥ 65 years)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

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.

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