

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)

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Study

Planned

Administrative details

EU PAS number

EUPAS1000000480

Study ID

1000000480

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

The primary objective is to evaluate Abrysvo® vaccine effectiveness (VE) against hospitalization for RSV-related respiratory tract disease in adults aged 60 and older stratified by immunocompromised status.

Study status

Planned

Research institutions and networks

Institutions

Copenhagen University Hospital – Herlev and Gentofte

Contact details

Study institution contact

Sine Hojlund Christensen

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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

Data analysis start date

Planned: 31/05/2025

Date of interim report, if expected

Planned: 30/09/2025

Date of final study report

Planned: 31/12/2027

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

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

Name of medicine

ABRYSVO

Name of medicine, 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

Population studied

Short description of the study population

The study population will include Danish adults aged 60+ year of age.

Age groups

Adults (46 to < 65 years)

Elderly (\geq 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Immunocompromised

Data management

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