Impact of EU label changes and regulatory communication on SARS-CoV-2 adenovirus vector vaccines in context of thrombosis with thrombocytopenia syndrome (TTS): risk awareness and adherence (RiskAwareTTS)

First published: 05/01/2022

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44970

Study ID

49546

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Greece
- [ ] Latvia
- [ ] Netherlands
- [ ] Portugal
- [ ] Slovenia

Study description

The European Medicines Agency (EMA) has provided recommendations to learned societies and healthcare professionals (HCPs) when assessing people with signs and symptoms of thrombosis with thrombocytopenia syndrome (TTS) after being vaccinated with Vaxzevria or COVID-19 Vaccine Janssen. In addition, the EMA also published safety updates on these vaccines, highlights from expert meetings and news items on its website. This study aims to evaluate the impact of the regulatory actions for Vaxzevria and for COVID-19 Vaccine Janssen following the 2021 review. In this context, the impact of regulatory actions means looking into: Whether HCPs are aware and know about the risk of TTS when administering these vaccines, Whether attitudes of HCPs and general public have changed towards national COVID-19 vaccination programmes, Whether national COVID-19 vaccination policies were altered following the regulatory actions.

Study status

Finalised

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

Department of Social Pharmacy, Faculty of pharmacy, University of Ljubljana

Slovenia

First published: 15/12/2021

Last updated: 20/08/2024

Institution | Educational Institution

Pharmacoepidemiology Research Collaboration (PRC), University of Copenhagen

Denmark

First published: 18/04/2017

Last updated: 24/03/2023

Institution | Educational Institution | ENCePP partner

Porto Pharmacovigilance Centre, Faculty of Medicine, University of Porto (UFPorto)

Portugal

First published: 17/11/2010

Last updated: 12/06/2023

Institution | Educational Institution | ENCePP partner

Centre for Health Protection (RIVM-GZB), National Institute for Public Health & Environment

Netherlands

First published: 06/11/2022

Last updated: 27/03/2024

Institution | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

Department of Medicine/Laboratory of Hygiene and Environmental Protection, Democritus University of Thrace

Greece

First published: 30/11/2022

Last updated: 05/12/2022

Institution | Educational Institution | ENCePP partner

Institute of Public Health, Riga Stradins University

Riga, Latvia

Networks

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands

First published: 01/02/2024

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Network

Contact details

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Primary lead investigator

Olaf Klungel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/11/2021

Actual: 04/11/2021

Study start date

Planned: 18/04/2022

Actual: 23/05/2022

Data analysis start date

Planned: 16/05/2022

Actual: 16/05/2022

Date of final study report

Planned: 30/03/2023

Actual: 26/05/2023

Sources of funding

- EMA

Study protocol

Protocol ROC24_COVID-19_vaccines_TTS 4.pdf(759.72 KB)

080422 Protocol RiskAware TTS version 3.0 final2.pdf(1.28 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

If ‘other’, further details on the scope of the study

Risk communication

Data collection methods:

Primary data collection

Main study objective:

To determine: 1) how regulatory actions for TTS have changed national vaccination policy, 2) level of HCP awareness and knowledge of the risk of TTS and adherence to SmPC recommendations for SARS-CoV2 adenovirus vaccines, 3) the extent of change in HCPs' attitudes towards COVID-19 national vaccination campaigns, 4) extent of change in citizens’ attitudes towards vaccination against SARS-COV2.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Web-based questionnaires with subsequent quantitative and qualitative analysis, and semi-structured telephone or online interviews

Study drug and medical condition

Medical condition to be studied

Thrombosis with thrombocytopenia syndrome

Population studied

Short description of the study population

The study cohort included: Work package 1, which involved six EU member states: Denmark, Greece, Latvia, Netherlands, Portugal, and Slovenia.
Work package 2 involved an inventory to identify participants for interviews, including those treating thrombosis with thrombocytopenia syndrome (TTS) in each country. It also included an inventory to recruit relevant professionals.
Work package 3 selected the most suitable strategy to obtain a sample of their adult population, aimed to recruit diverse responders from different sociodemographic subgroups.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with thrombosis with thrombocytopenia syndrome

Estimated number of subjects

1400

Study design details

Outcomes

The impact of the 2021 EU regulatory actions for Vaxzevria and for COVID-19 Vaccine Janssen following the 2021 review namely: Alterations to national COVID-19 vaccination policies, Awareness and knowledge among HCP about the risk of TTS when administering these vaccines, Changes to attitudes of HCPs and general public towards national COVID-19 vaccination programmes.

Data analysis plan

Each National Team will provide the overview and timeline of COVID-19 vaccination policies to the Study Coordinator for compilation according to a standardised and agreed format. The surveys will generate descriptive statistics with univariate and bivariate analyses of variables. Given the variation in vaccination policies, survey data will be analysed at national level. For the qualitative data, the analysis involves a deductive content analysis based on a line-by-line reading of the responses and developing a conceptual coding scheme based on major themes in the interview. Transcripts will be coded individually by two researchers in each country in their native languages. Processing of personal data will comply with the EU data protection legislation and GDPR. Citizens and HCPs will participate anonymously in the questionnaires and interviews. Only fully anonymised data will be shared with the coordinating team. Ethical approval and participants' informed consent will be acquired.

Documents

Study results

RiskAware TTS Summary ENCEPP_SA.pdf(334 KB)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

All COI forms-Annex5.pdf(2.17 MB)

Composition of steering group and observers

Teams in RiskAware TTS project.pdf(104.33 KB)

Signed code of conduct

empty_file_1.pdf(11.35 KB)

Signed code of conduct checklist

empty_file_1.pdf(11.35 KB)

Signed checklist for study protocols

empty_file_1.pdf(11.35 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, cross-sectional survey among HCPs and citizens, semi-structured interviews

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

No