A Nested Case-Control Post-Authorization Effectiveness Study: The Association Between Prior Exposure to Dengue Tetravalent Vaccine (Live, Attenuated) (TDV) and Dengue Hospitalization in a Pediatric and Adolescent Population

First published: 24/02/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000218

Study ID

1000000218

DARWIN EU® study

No

Study countries

Indonesia

Malaysia

Thailand

Study description

The main aim of this study is to collect more information on the effectiveness of TDV when used in a pilot public vaccination program for children and adolescents participating in a community-based cohort in Southeast Asian countries with high dengue transmission, specifically Thailand, Indonesia, and Malaysia where TDV is already approved for use.

The study will include cohort participants (individual follow-up of 3 years) who may or may not later be vaccinated with TDV as part of a pilot public vaccination program in the study countries.
The study will investigate if cohort participants who were vaccinated with TDV have less hospital stays due to dengue than cohort participants who were not vaccinated with TDV. The study will also provide further information on the effectiveness of TDV against the least common dengue virus serotypes (DENV-3 and DENV-4).

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/08/2024

Actual: 27/09/2024

Study start date

Planned: 05/03/2025

Actual: 05/03/2025

Data analysis start date

Planned: 30/06/2029

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

DEN-401-clinical-study-protocol-redact.pdf (1.37 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

DEN-401, NCT06843226

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

In this observational, nested case-control study, the vaccination status of cohort participants hospitalized for virologically confirmed dengue (VCD) (cases) will be compared with that of participants who are not hospitalized for VCD (controls).

Main study objective:

To estimate the association between completed vaccination with TDV (as part of a vaccination program) and hospitalization due to VCD, including severe dengue.

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Cohort with nested case-control effectiveness investigation

Study drug and medical condition

Medicinal product name

QDENGA

Medicinal product name, other

Dengue Tetravalent Vaccine (Live, Attenuated) (TDV)

Anatomical Therapeutic Chemical (ATC) code

(J07BX04) dengue virus vaccines

dengue virus vaccines

Medical condition to be studied

Dengue fever

Population studied

Short description of the study population

Pediatric and/or adolescent residents in the study area who are age-eligible for vaccination with TDV as part of a pilot public vaccination program (children 7-10 years of age in Thailand, children 6-10 years of age in Indonesia, and children and adolescents 7-12 years of age in Malaysia).

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

70.000

Study design details

Outcomes

The primary outcome will assess:
Association between completed vaccination with TDV (as part of a vaccination program) and hospitalization due to VCD, including severe dengue

The secondary outcome will assess:
The association between completed vaccination with TDV (as part of a vaccination program) and subsequent hospitalization due to VCD, including severe dengue, by:
• The infecting dengue serotype (DENV 1, DENV 2, DENV 3, and DENV 4).
• The baseline dengue serostatus (seronegative and seropositive at baseline).
• The infecting dengue serotype and the baseline dengue serostatus.

Data analysis plan

Data analysis will be conducted using a conditional logistic regression model with odds ratio (OR) as the output.

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

Not applicable