# A Five-year, Observational, Non-interventional Follow-up to: A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Sitagliptin in Pediatric Patients with Type 2 Diabetes Mellitus with Inadequate Glycemic Control (MK-0431-351)

**First published:** 07/08/2013

**Last updated:** 06/12/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS4468

**Study ID**

49810

**DARWIN EU® study**

No

**Study countries**

- [ ] Argentina
- [ ] Brazil
- [ ] Canada
- [ ] Colombia
- [ ] Costa Rica
- [ ] Guatemala
- [ ] Honduras
- [ ] Hungary
- [ ] Israel
- [ ] Italy
- [ ] Lithuania
- [ ] Malaysia
- [ ] Mexico
- [ ] Philippines
- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] United States

**Study description**

This is a follow-up study of participants who participated in a multinational, placebo-controlled, double-blind, parallel-group study that assessed the safety and efficacy of sitagliptin once daily in pediatric participants (ages 10-17 years, inclusive at initiation of therapy) with T2DM with inadequate glycemic control. The objective is to provide an up to 5-year observational assessment of safety of participants with T2DM who were treated for up to one year with sitagliptin as initial monotherapy in the aforementioned study.

**Study status**

Finalised

## Research institutions and networks

### Institutions

Merck Sharp & Dohme Co. Ltd. Hod Hasharon, Israel, Phone number: 972 9 9539310

## Contact details

**Study institution contact**

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**Primary lead investigator**

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**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 23/01/2013

**Study start date**
Actual: 13/09/2013

**Data analysis start date**
Actual: 08/08/2024

**Date of final study report**
Actual: 27/11/2024

## Sources of funding

## More details on funding

Merck Sharp & Dohme LLC

## 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:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The objective is to provide an up to 5-year observational assessment of safety of participants with T2DM who were treated for up to one year with sitagliptin or metformin as initial monotherapy in a previous study.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Non-interventional observational follow-up study of a randomized clinical trial

## Study drug and medical condition

**Medicinal product name**

SITAGLIPTIN

**Study drug International non-proprietary name (INN) or common name**

SITAGLIPTIN

**Anatomical Therapeutic Chemical (ATC) code**

(A10BH01) sitagliptin

sitagliptin

**Medical condition to be studied**

Type 2 diabetes mellitus

# Population studied

**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

**Special population of interest**

Other

**Special population of interest, other**

Pediatric patients with Type 2 Diabetes Mellitus with Inadequate Glycemic Control

**Estimated number of subjects**

81

# Study design details

**Outcomes**

Number (%) of participants and follow-up adjusted incidence rates by treatment group for any adverse event (AE), AE system organ classes (SOC). Descriptive statistics by treatment group from a previous study for body mass index (BMI), body weight, height, Tanner Stage, growth velocity, diastolic and systolic blood pressure, pulse rate.

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**Data analysis plan**

Safety endpoints for the follow-up study will be summarized by treatment group from a previous study, with no between-group comparisons.

## Documents

**Study report**

MK-0431 P351 CSR_final-redaction.pdf (2.19 MB)

# 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 sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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