Treatment Patterns, and Treatment Outcomes Before and After Humulin R U-500 Initiation and Device Switch Among Type 2 Diabetes Patients in the United States Treated with a Total Daily Dose of ≤ 200 Units of Insulins per Day (U-500R Lower Dose Cohort)

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Study Finalised

Administrative details

EU PAS number

EUPAS32169

Study ID

39152

DARWIN EU® study

No

Study countries

United States

Study description

The study is a retrospective real-world study using Veteran Health Administration database to evaluate treatment patterns and treatment outcomes before and after U-500R exposure among T2DM patients who utilized less ≤200 units/day of insulins either before or after U-500R exposure

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

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Primary lead investigator

Jieling Chen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/09/2019

Actual: 09/09/2019

Study start date

Planned: 11/11/2019

Actual: 15/11/2019

Data analysis start date

Planned: 29/11/2019

Date of final study report

Planned: 31/12/2019

Actual: 05/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

SIMR_Eli Lilly_Protocol lower-Dose_VHA_Final.pdf (784.62 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To understand the treatment pattern and outcomes before and after U-500R exposure among those who utilized <=200 units of insulin either before or after U-500R exposure

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

INSULIN

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Type 2 diabetes mellitus (T2DM) patients who utilized less ≤200 units/day of insulins either before or after U-500R exposure.

Patient Selection Criteria for the U-500R Syringe Initiators:

Inclusion criteria

Patient will be included in this cohort if they:

- had ≥1 prescription claim for U-500R vial during the identification period (01JAN2014–30JUN2017), with the first prescription claim for U-500R vial designated as Index Event a (U-500R syringe initiation), and the date designated as the index date;
- had ≥2 claims with an ICD-9/10-CM code (Appendix 1) for T2DM in any position (primary/secondary) at any time prior to the index date
- were aged ≥18 years on the index date;
- had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- had ≥1 prescription claim for any insulin other than U-500R in the 9-month pre-index period;
- had ≥1 HbA1c measurement within 90 days pre-index or 30 days post-index event;
- had ≥1 HbA1c measurement after the 30-day post-index period at any time in the 9-month follow-up period; and

Exclusion criteria

Patient will be excluded in this cohort if they:

- had both T1DM and T2DM, had no oral anti-diabetic drug (OADs; Appendix 1) other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (01APR2013–31MAR2018).
- had previous use of U-500R in the 9-month pre-index period;
- had ≥1 claim with an ICD-9/10-CM code (Appendix 1) for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or nonclinical diabetes at any time during the 9-month pre-index period;
- had claims indicating pump use (Appendix 2) in the 9-month post-index (follow-up) period;
- had claims indicating TDD above 2000 units/day at any time in the pre-index

or postindex periods; or

- had TDD >200 units/day both in the pre- and post-index periods

Patient Selection Criteria for U-500R Kwikpen Initiators:

Inclusion criteria

Patient will be included in this cohort if they:

- had ≥1 prescription claim for U-500R Kwikpen administration during the identification period (01JAN2014–30JUN2017), with the first prescription claim for U-500R Kwikpen administration designated as Index Event b, and the date designated as the index date;
- had ≥2 claims with an ICD-9/10-CM code (Appendix 1) for T2DM in any position (primary/secondary) at any time prior to the index date;
- were aged ≥18 years on the index date;
- had continuous health plan enrolment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- had ≥1 prescription claim for any insulin other than U-500R (Table 1) in the 9-month pre-index period;
- had ≥1 HbA1c measurement within 90 days pre-index or 30 days post-index event; and
- had ≥1 HbA1c measurement after the 30-day post-index period at any time in the 9-month post-index period.

Exclusion criteria

Patient will be excluded in this cohort if they:

- had both T1DM and T2DM, had no OADs (Appendix 1) other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (01APR2013–31MAR2018);

- had previous use of U-500R in the 9-month pre-index period;
- had ≥1 claim with an ICD-9/10-CM code (Appendix 1) for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or nonclinical diabetes at any time during the 9-month pre-index period;
- had evidence of pump use (Appendix 2) in the 9-month post-index period;
- had claims indicating TDD above 2000 units/day at any time in the pre-index or postindex periods; or
- had TDD >200 units/day in the 9 months pre- and post-index periods.

Patient Selection Criteria for any U-500R Initiators:

Inclusion criteria

Patient will be included in this cohort if they:

- had ≥1 prescription claim for U-500R syringe/Kwikpen administration during the identification period (01JAN2014–30JUN2017), with the first prescription claim for U-500R syringe or Kwikpen administration designated as Index Event c, and the date designated as the index date;
- had ≥2 claims with an ICD-9/10-CM code (Appendix 1) for T2DM in any position (primary/secondary) at any time prior to the index date;
- were aged ≥18 years on the index date;
- had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- had ≥1 prescription claim for any insulin other than U-500R (Table 1) in the 9-month pre-index period;
- had ≥1 HbA1c measurement within 90 days pre-index or 30 days post-index event; and
- had ≥1 HbA1c measurement after the 30-day post-index period at any time in the 9-month post-index period.

Exclusion criteria

Patient will be excluded in this cohort if they:

- had both T1DM and T2DM, had no OADs (Appendix 1) other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (01APR2013-31MAR2018);
- had previous use of U-500R in the 9-month pre-index period;
- had ≥1 claim with an ICD-9/10-CM code (Appendix 1) for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or nonclinical diabetes at any time during the 9-month pre-index period;
- had evidence of pump use (Appendix 2) in the 9-month post-index period;
- had claims indicating TDD above 2000 units/day at any time in the pre-index or postindex periods; or
- had TDD >200 units/day in the pre- and post-index periods.

Patient Selection Criteria for U-500R Device Switchers from Syringe to Kwikpen

Inclusion criteria

Patient will be included in this cohort if they:

- had ≥1 claim for U-500R Kwikpen administration in the identification period (01JAN2014–30JUN2017), with the first prescription claim for U-500R Kwikpen administration designated as Index Event 2, and the date designated as the index date;
- had ≥2 claims with an ICD-9/10-CM code (Appendix 1) for T2DM in any position (primary/secondary) at any time prior to the index date;
- were aged ≥18 years on the index date;
- had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- had ≥1 prescription claim for U-500R vial use in the 9-month pre-index period;
- had ≥1 HbA1c measurement within 90 days pre-index event or 30 days post-index event; and
- had ≥1 HbA1c measurement after the 30-day post-index period.

Exclusion criteria

Patient will be excluded in this cohort if they:

- had both T1DM and T2DM, had no OADs (Appendix 1) other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (01APR2013–31MAR2018);

had previous use of U-500R Kwikpen administration in the 9-month pre-index period;

- had ≥1 claim with an ICD-9/10-CM code (Appendix 1) for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or nonclinical diabetes at any time during the 9-month pre-index period;
- had claims indicating pump use (Appendix 2) in the 9-month post-index period;
- had claims indicating TDD exceeding 2000 units/day at any time in the pre-index or post-index periods; or
- had TDD >200 units/day in the pre- and post-index periods.

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

Type 2 diabetes mellitus patients

Estimated number of subjects

1200

Study design details

Outcomes

Treatment Patterns and HbA1c, Hypoglycemia

Data analysis plan

This will be a retrospective cohort study using the Veterans Health Administration (VHA) database. 1. The first prescription claim date for U-500R syringe or U-500R Kwikpen administration will be considered U-500R initiation and designated as Index Event 1 (syringe: Index Event 1a, Kwikpen: Index Event 1b, any U-500R use: Index Event 1c). 2. The date for U-500R device switch from syringe to Kwikpen will be designated as Index Event 2. 3. The study period will range from 01APR2013–31MAR2018. 4. The identification period will be 01JAN2014–30JUN2017, the pre-index and post-index (follow-up) periods will be 9 months, respectively

Documents

Study results

EUPAS32169-39150.pdf (4.68 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)

Administrative healthcare records (e.g., claims)

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