Treatment Patterns, Treatment Outcomes, and Health Care Costs Before and After Humulin R U-500 Initiation or Device Change among Patients with Type 2 Diabetes in the United States (U500 RWE)

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Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39154

Study ID

39155

DARWIN EU® study

No

Study countries

United States

Study description

1. Examine treatment patterns before an after U-500R initiation/Device Change,

2. Understand factors associated with observed treatment pattern changes,

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Jieling Chen chen_jieling@lilly.com

Study contact

chen_jieling@lilly.com

Primary lead investigator

Jieling Chen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/09/2018

Actual: 30/09/2018

Study start date
Planned: 01/10/2018

Actual: 01/10/2018

Data analysis start date
Planned: 01/11/2018

Actual: 01/11/2018

Date of final study report
Planned: 05/01/2021

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_VHA Truven_U-500R_Final.pdf (507.62 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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Understand the treatment pattern and clinical outcomes before and after U-500R initiation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Humulin R U-500

Medical condition to be studied

Insulin-requiring type 2 diabetes mellitus

Population studied

Short description of the study population

Patient selection criteria for the U-500R Syringe Initiators [Index Event 1a]:

- Include patients who had ≥1 prescription claim for U-500R vial during the identification period (VHA and LCED: 01JAN2014-30JUN2017; Truven: 01APR2014-30SEP2017)—the first prescription claim for U-500R vial will be designated as index Event 1a (U-500R syringe initiation), and the date will be designated as the index date;
- Include patients who had ≥2 claims with an ICD-9/10-CM code for T2DM in any position (primary/secondary) at any time prior to the index date;

- Exclude patients who had both T1DM and T2DM, had no oral anti-diabetic drug (OADs) other than metformin, and the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (VHA and LCED: 01APR2013-31MAR2018; Truven: 01JUL2013-30JUN2018);
- Include patients who were aged ≥18 years on the index date;
- Include patients who had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- Exclude patients with no evidence of insulin including U-500R (any type; Table 2) in the 9 months pre-index period (baseline);
- Exclude patients with ≥1 prescription claim for U-500R use in the 9 months pre-index period;
- Include patients who had ≥1 prescription claim for any insulin other than U-500R in the 9-month pre-index period;
- Include patients who had ≥1 HbA1c measurement within 90-day pre-index or 30-day post-index event;
- Include patients who had ≥1 HbA1c measurement after the 30-day post-index period at any time in the 9-months follow-up period;

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within 30 days prior to the end of the 9-months follow-up period will be flagged; and

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within 2 months prior to the end of the 9-months follow-up period will be flagged;

- Exclude patients who had ≥1 claim with a ICD-9/10-CM code for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, or puerperium, or non-clinical diabetes at any time during the 9-month baseline period;
- Exclude patients who had claims indicating pump use (Appendix 2) in the 9-month post-index (follow-up) period;
- Exclude patients who had claims indicating TDD above 2000 units/day at any time in the pre-index or post-index periods.

Sample selection criteria for U-500R Kwikpen Initiators [Index Event 1b]

- Include patients who had ≥1 prescription claim for U-500R Kwikpen administration during the identification period (VHA and LCED: 01JAN2014-30JUN2017; Truven: 01APR2014-30SEP2017)–the first prescription claim for U-500R Kwikpen administration will be designated as Index Event 1b, and the date will be designated as the index date;
- Include patients who had ≥2 claim with an ICD-9/10-CM code for T2DM in any position (primary/secondary) at any timeprior to the index date;
- Exclude patients who had both T1DM and T2DM, had no OADs other than metformin, and the ratio between the number of T1DM and T2DM claims >0.5 at

any time in the study period (VHA and LCED: 01APR2013-31MAR2018; Truven: 01JUL2013-30JUN2018);

- Include patients who were aged ≥18 years on the index date;
- Include patients who had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- Exclude patients with no evidence of insulin including U-500R (any type) in the 9 months pre-index period (baseline);
- Exclude patients with ≥1 prescription claim for U-500 use in the 9 months pre-index period;
- Include patients who had ≥1 prescription claim for any insulin other than U-500R in the 9-month pre-index period;
- Include patients who had ≥1 HbA1c measurement within 90-day pre-index or 30-day post-index event;
- Include patients who had ≥1 HbA1c measurement after the 30-day post-index period at any time in the 9-months follow-up period;

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within 30 days prior to the end of the 9-months follow-up period will be flagged; and

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within

2 months prior to the end of the 9-months follow-up period will be flagged;

- Exclude patients who had ≥1 claim with a ICD-9/10-CM code for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, or puerperium, or non-clinical diabetes at any time during the 9-month baseline period;
- Exclude patients who had evidence of pump use in the 9-month followup period;
- Exclude patients who had claims indicating TDD above 2000 units/day at any time in the pre-index or post-index periods.

Sample Selection Criteria for U-500R Device Switchers from Syringe to Kwikpen [Index Event 2]

- Include patients who had ≥1 claim for U-500R Kwikpen administration in the identification period (VHA and LCED: 01JAN2014-30JUN2017; Truven: 01APR2014-30SEP2017)–the first prescription claim for U-500R Kwikpen administration will be designated as the Index Event 2, and the date will be designated as the index date;
- Include patients who had ≥2 claim with an ICD-9/10-CM code for T2DM in any position (primary/secondary) at any timeprior to the index date;
- Exclude patients who had both T1DM and T2DM, had no OADs other than metformin, and the ratio between the number of T1DM and T2DM claims >0.5 at

any time in the study period (VHA and LCED: 01APR2013-31MAR2018; Truven: 01JUL2013-30JUN2018);

- Include patients who were aged ≥18 years on the index date;
- Include patients who had continuous health plan enrollment with medical and pharmacy benefits for ≥9 months pre- and post-index event;
- Include patients who had ≥1 prescription claim for U-500R vial use in the 9-month baseline period;
- Include patients who had ≥1 HbA1c measurement within 90-day pre-index

event or 30-day post-index event; and

 Include patients who had ≥1 HbA1c measurement after the 30-day post-index period;

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within 30 days prior to the end of the 9-months follow-up period will be flagged; and

o Patients with ≥1 HbA1c measurement after the 30-day post-index and within 2 months prior to the end of the 9-months follow-up period will be flagged;

 Exclude patients who had ≥1 claim for U-500R Kwikpen administration in the 9-month baseline period;

 Exclude patients who had ≥1 claim with a ICD-9/10-CM code for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, or puerperium, or non-clinical diabetes at any time during the 9-month baseline period;

 Exclude patients who had claims indicating pump use in the identification period;

 Exclude patients who had claims indicating TDD exceeding 2000 units/day at any time in the pre-index or 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

2500

Study design details

Outcomes

HbA1c, hypoglycemia

Data analysis plan

pre and post study design

Documents

Study results

EUPAS39154-39158.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