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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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

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Study contact

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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

2.500

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

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