Treatment Patterns, Treatment Outcomes, and Out-of-Pocket Pharmacy Costs Before and After Humulin R U-500 Initiation Among Type 2 Diabetes Patients in the United States Utilizing a Total Daily Dose of >180 units per Day (High Dose U500)

First published: 22/01/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39161

Study ID

39162

DARWIN EU® study

No

Study countries

United States

Study description

Evaluate HbA1c, Hypoglycemia, adherence, and out-of-pocket costs before and after U-500R initiation in real-world setting among the patients who used U-500R in the way that was consistent with label

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

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: 01/09/2018

Actual: 05/05/2019

Study start date
Planned: 01/10/2018

Actual: 05/06/2019

Date of final study report
Planned: 31/12/2020

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 High-Dose Cohort_Final_to_LEO.pdf

(749.35 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:

Evaluate HbA1c, Hypoglycemia, and adherence before and after U-500R initiation in real-world setting among the patients who used U-500R in the way that was consistent with label

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

U-500R Syringe Initiators [Index Event a]

Inclusion Criteria

Patient will be included if they:

 had ≥1 prescription claim for U-500R vial during the identification period (VHA: 01JAN2014–30JUN2017; Truven: 01JUL2014–30JUN2017), 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 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 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 post-index period;
- had claims indicating TDD >180 in the post-index period;
- had claims indicating TDD >180 in the pre-index period; and

Exclusion Criteria

Patient will be excluded if they:

- had both T1DM and T2DM, had no oral anti-diabetic drug (OADs; Appendix 1) other than metformin, and the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (VHA: 01APR2013–31MAR2018; Truven: 01JUL2013–30JUN2018);
- had previous use of U-500R in the 9-month pre-index period;
- had ≥1 claim with an ICD-9/10-CM code for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or non-clinical diabetes at any time during the 9-month pre-index period;
- had claims indicating pump use 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 post-index periods; or
- had claims indicating insulin use other than U-500R in the post-index period.

U-500R Kwikpen Initiators [Index Event b]

Inclusion Criteria

Patient will be included if they:

- had ≥1 prescription claim for U-500R Kwikpen administration during the identification period (VHA: 01JAN2014–30JUN2017; Truven: 01JUL2014–30JUN2017), 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 claim with an ICD-9/10-CM code 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 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 followup period;
- had claims indicating TDD >180 in the post-index period;
- had claims indicating TDD >180 in the pre-index period; and

Exclusion Criteria

Patient will be excluded if they:

- had both T1DM and T2DM, had no OADs other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study period (VHA: 01APR2013–31MAR2018; Truven: 01JUL2013–30JUN2018);
- had previous use of U-500R in the 9-month pre-index period;
- had ≥1 claim with a ICD-9/10-CM code (Appendix 1) for secondary diabetes, gestational diabetes, diabetes complicating pregnancy, childbirth, puerperium, or non-clinical diabetes at any time during the pre-index period;

- had evidence of pump use in the post-index period;
- had claims indicating TDD above 2000 units/day at any time in the pre-index or post-index periods; or
- had claims indicating insulin use other than U-500R in the post-index period.

Sample selection criteria for any U-500R Initiators [Index Event c]

Inclusion Criteria

Patient will be included if they:

- had ≥1 prescription claim for U-500R syringe or Kwikpen administration during the identification period (VHA: 01JAN2014–30JUN2017; Truven: 01JUL2014– 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 claim with an ICD-9/10-CM code 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 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 followup period;
- had claims indicating TDD >180 in the post-index period; and
- had claims indicating TDD >180 in the pre-index period

Exclusion Criteria

Patient will be excluded if they:

- had both T1DM and T2DM, had no OADs other than metformin, with the ratio between the number of T1DM and T2DM claims >0.5 at any time in the study

period (VHA: 01APR2013–31MAR2018; Truven: 01JUL2013–30JUN2018);

- had previous use of U-500R in the 9-month pre-index period;
- 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 pre-index period;
- had evidence of pump use in the follow-up period;
- had claims indicating TDD above 2000 units/day at any time in the pre-index or post-index periods; or
- had claims indicating insulin use other than U-500R in the post-index period.

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

1.000

Study design details

Outcomes

HbA1c, Hypoglycemia, adherence

Data analysis plan

pre and post design

Documents

Study results

EUPAS39161-39160.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