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

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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: 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

Name of medicine, 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

1000

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

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