# 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

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**Primary lead investigator**

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**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/09/2018

Actual: 05/05/2019

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**Study start date**

Planned: 01/10/2018

Actual: 05/06/2019

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**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

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**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

## 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