It's Time to discover

The ULTRAFLEXI-1 study design

Toujeo®
insulin glargine 300U/mL

EASD and ADA recommend regular physical activity for people with diabetes[1,2]

Fear of hypoglycemia is the major barrier to incorporating exercise into daily life[3,4]

ULTRAFLEXI-1 is the first randomized controlled trial to compare Toujeo® and degludec 100 U/mL, in people with T1DM who exercise, using Time-below-Range as the primary endpoint[5]

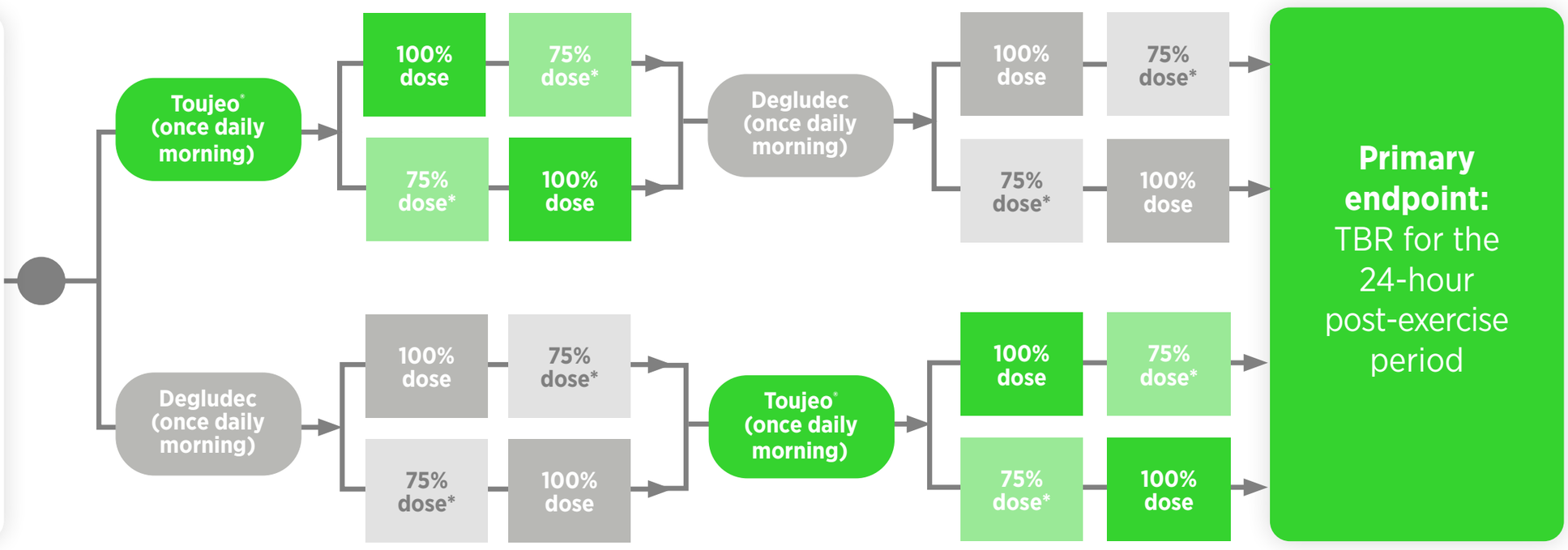
NOW PUBLISHED

Toujeo® insulin glargine 300U/mL | HEAD TO HEAD | TBR | TYPE 1 DIABETES | Degludec 100 U/mL

A ROBUSTLY DESIGNED, RANDOMIZED, ACTIVE-CONTROLLED, FOUR-PERIOD, CROSS-OVER STUDY[5-7]

Eligible patients

- Adults (18–65 years) with T1DM (≥ 12 months) performing regular physical cardio-respiratory activity during the last 3 months prior to screening
- HbA_{1c} ≤10%
- ≥ 1 year MDI injections
- BMI 18.0-29.9 kg/m²
- Mass-specific peak oxygen consumption (VO_{2peak}) >20 ml/kg/min



Primary endpoint[5]: Time-below-Range (<70 mg/dL)‡ during the 24-hour post-exercise periods of six spontaneous exercise sessions in the four trial arms on either a regular (100%) or reduced (75%) Toujeo® and degludec 100 U/mL dose

Secondary endpoints included[5]: TIR (70-180 mg/dL)¥, TBR (<54 mg/dL)¶, TAR (181-250 mg/dL)# and TAR (>250 mg/dL)** for the 24-hour post-exercise periods, during exercise periods and for the entire intervention period (overall)

Want to **know more**? Any questions? We are here to discuss...

Toujeo® is indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.[8]
The most common adverse events are hypoglycemia (very common), lipohypertrophy and injection site reactions (common).[8]
This material is intended for healthcare professionals only. For more information please consult the [country to insert link to local regulatory document e.g. SmPC].

*On non-exercise days within the 2 week exercise period, participants remained on the same type of basal insulin, administering the regular basal insulin dose (100%);[5] †CGM was blinded during the non-exercise periods to the participants. During the exercise sessions, real-time CGM was unblinded to avoid exercise-induced dysglycemia, and therapy adaptations were performed based on the recent EASD/ISPAD position statement;[5] ‡3.9 mmol/L; ¥3.9– 10.0 mmol/L; ¶3.0 mmol/L ; #10.1-13.9 mmol/L; **13.9 mmol/L.[5]

Abbreviations: ADA, American Diabetes Association; BMI, body mass index; CGM, continuous glucose monitoring; Degludec, insulin degludec 100 U/mL; EASD, European Association for the Study of Diabetes; HbA_{1c}, hemoglobin A_{1c}; ISPAD, International Society for Pediatric and Adolescent Diabetes; MDI, multiple daily injections; T1DM, type 1 diabetes mellitus; TAR, time-above-range; TBR, time-below-range; TIR, time-in-range.

References: 1. ADA Standards of Medical Care in Diabetes 2022;45(Suppl. 1):S60–S82; 2. Holt RI, e*t al. Diabetes Care* 2021;44(11):2589–2625; 3. Moser O, *et al*. EASD Position statement 2020. Available at: https://www.easd.org/sites/default/files/Exercise CGM EASD position statement_final.pdf. [Last accessed in January 2023]; 4. Yardley JE, Sigal RJ. *Diabetes Spectr* 2015;28:32-8; 5. Moser O, *et al. Diabetes Technol Ther* 2022;doi: 10.1089/dia.2022.0422; 6. EU Clinical Trials Register. ULTRAFLEXI-1. Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-003209-89/AT. [Last accessed in January 2023]; 7. Moser O, et al. The ULTRAFLEXI-1 study. Poster presentation 39-LB. ADA Scientific sessions meeting, New Orleans, LA, US June 2022; 8. Toujeo® European Summary of Product Characteristics. [insert date] [country to adapt to local regulatory document].

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