Trial Review

VIEW TRIAL AT REGISTRATION VIEW HISTORY

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been endorsed by the ANZCTR. Before participating in a study, talk to your health care provider and refer to this information for consumers

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Trial registered on ANZCTR

Registration number	ACTRN12623001236684
Ethics application status	Approved
Date submitted	21/09/2023
Date registered	30/11/2023
Date last updated	15/12/2024
Date data sharing statement initially provided	30/11/2023
Type of registration	Prospectively registered

Titles & IDs

Public title	The Combination of Tirzepatide and Resistance EXercise (T-REX) for the Management of Body Composition
Scientific title	A parallel group superiority trial comparing the impacts of Tirzepatide, and the combination of Tirzepatide and Resistance Exercise training (T-REX), on body composition and cardiovascular variables, in community dwelling men and post-menopausal women with overweight and obesity
Secondary ID [1]	None
Universal Trial Number (UTN)	
Trial acronym	T-REX
Linked study record	

Health condition

Health condition(s) or problem(s) studied:	
Obesity	
Overweight	
Condition category	**Condition code**
Metabolic and Endocrine	Normal metabolism and endocrine development and function
Physical Medicine / Rehabilitation	Other physical medicine / rehabilitation

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	Tirzepatide (background therapy, given to all participants): Doses will be administered as once weekly subcutaneous injections by a research nurse or other qualified research personnel at the study centre. Tirzepatide will be initiated at a dose of 2.5 mg once weekly and increased by 2.5 mg every 4 weeks during the dose-escalation period aiming to reach a maintenance dose of 15 mg once weekly by week 20. Therapy at this dose will continue at either the maximum tolerated dose or at 15 mg for a further 20 weeks (40 weeks' intervention in total). This intervention period allows for attainment of metabolic benefit and provision of centre-based and supervised exercise interventions, described below. Exercise intervention:

Eli Lilly & Co.
Exhibit 2050
BPI Labs v. Eli Lilly
IPR2025-01346
Ex. 2050-001

Description of intervention(s) / exposure	Tirzepatide (background therapy, given to all participants): Doses will be administered as once weekly subcutaneous injections by a research nurse or other qualified research personnel at the study centre. Tirzepatide will be initiated at a dose of 2.5 mg once weekly and increased by 2.5 mg every 4 weeks during the dose-escalation period aiming to reach a maintenance dose of 15 mg once weekly by week 20. Therapy at this dose will continue at either the maximum tolerated dose or at 15 mg for a further 20 weeks (40 weeks' intervention in total). This intervention period allows for attainment of metabolic benefit and provision of centre-based and supervised exercise interventions, described below. Exercise intervention: Participants randomised to the exercise groups will attend 3 x one-hour exercise sessions per week for 40 weeks. Participants will exercise in group sessions and the program will focus on increasing skeletal muscle mass and function. Exercise sessions will be undertaken in a dedicated research gym at the University of Western Australia, supervised by an Accredited Exercise Physiologist (AEP). The exercise training program will be in line with recommendations for the prescription and programming of resistance training, endorsed by Exercise and Sport Science Australia (ESSA). Exercise will commence with light-moderate intensity exercises and focus on developing correct technique, whilst the participants become accustomed to resistance training. Over the course of the 40-week training program, the intensity will gradually increase to moderate-vigorous exercise. Each 1 hr session will consist of a general whole body warm up, followed by resistance-based exercises involving major muscle groups using a variety of apparatus, including bodyweight exercises, bands, cables, machines, and free-weights. Example exercises are squats, deadlifts, leg-press, lateral pulldowns, shoulder press and chest press. Each session will conclude with a 5 min cool down. Borg's Category Scale will be used to rate perceived exertion during session. A record of attendance will be kept.
Intervention code [1]	Treatment: Drugs
Intervention code [2]	Treatment: Other
Comparator / control treatment	The non-training (tirzepatide only) group will be required to attend one session per week across the 40 week intervention phase to obtain their weekly tirzepatide dose, and to perform strength testing at the same time points as the exercise training groups, This attendance will ensure compliance with the drug regimen and also provide a basis to account for the Hawthorne effect.
Control group	Active

Outcomes

Primary outcome [1]	Change in lean mass will be assessed using dual energy X-ray absorptiometry (DXA)
Timepoint [1]	Pre-intervention (week 0), during the intervention (at 8, 16, 24, 32 weeks post-baseline). Post-intervention (40 weeks post-baseline - primary timepoint) and follow-up (week 56 post-baseline).
Primary outcome [2]	Change in fat mass will be assessed using dual energy X-ray absorptiometry (DXA)
Timepoint [2]	Pre-intervention (week 0), during the intervention (at 8, 16, 24, 32 weeks post-baseline). Post-intervention (40 weeks post-baseline - primary timepoint) and follow-up (week 56 post-baseline)
Secondary outcome [1]	Skeletal muscle function: One repetition maximum (1RM) muscle strength testing.
Timepoint [1]	Weeks 0, 8, 16, 24, 32 ,40 and 56 weeks post-baseline
Secondary outcome [2]	Cardiopulmonary fitness: Graded exercise test VO2peak test Cardiorespiratory fitness will be assessed via a graded exercise treadmill test with analysis of continuous expired air using a metabolic cart.
Timepoint [2]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [3]	Endothelial function will be assessed in the brachial and femoral arteries using non-invasive, high resolution Duplex ultrasound. The flow-mediated dilation (FMD%) increase in artery dilation is an indicator of artery function and independently predicts CV events. Endothelium-independent dilation is examined using a single, 400 µg sublingual administration of glyceryl trinitrate. Carotid intima-media thickness will be measured using ultrasound.
Timepoint [3]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [4]	Skin microvascular function will be measured using Optical Coherence Tomography (OCT) imaging (which is non-invasive).
Timepoint [4]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [5]	Cardiac mechanics will be assessed via transthoracic echocardiography
Timepoint [5]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [6]	Resting blood pressure will be measured using an automated dynamometer (Dinamap).
Timepoint [6]	Weeks 0, 8, 16, 24, 32, 40 and 56 post-baseline
Secondary outcome [7]	Body mass will be measured using electronic scales
Timepoint [7]	Weeks 0,8,16,24,32,40,56 post-baseline
Secondary outcome [8]	Physical activity will be recorded for a 7-day period, using a small, wearable accelerometer.
Timepoint [8]	Weeks 0, 8, 24, 40 and 56 post-baseline
Secondary outcome [9]	Full-blood count, from blood sample.
Timepoint [9]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [10]	Waist girth will be measured using a constant-tension tape measure
Timepoint [10]	Weeks 0,8,16,24,32,40,56 post-baseline

Secondary outcome [8]	Physical activity will be recorded for a 7-day period, using a small, wearable accelerometer.
Timepoint [8]	Weeks 0, 8, 24, 40 and 56 post-baseline
Secondary outcome [9]	Full-blood count, from blood sample.
Timepoint [9]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [10]	Waist girth will be measured using a constant-tension tape measure
Timepoint [10]	Weeks 0,8,16,24,32,40,56 post-baseline
Secondary outcome [11]	BMI will be calculated from measured weight (digital scales) and height (stadiometer).
Timepoint [11]	Weeks 0,8,16,24,32,40,56 post-baseline
Secondary outcome [12]	Urine samples of 2 mls will be collected and stored at -80 C for future research-related assays.
Timepoint [12]	Weeks 0, 8, 16, 24, 32, 40 and 56 post-baseline
Secondary outcome [13]	Urea/electrolytes, from blood sample.
Timepoint [13]	Weeks 0, 8, 24, 40 and 56 post-baseline
Secondary outcome [14]	Liver function, from blood sample.
Timepoint [14]	Weeks 0, 8, 24, 40 and 56 post-baseline
Secondary outcome [15]	Glycated haemoglobin (HbA1c) from blood sample.
Timepoint [15]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [16]	Blood glucose, from blood sample
Timepoint [16]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [17]	Lipid profile, from blood sample.
Timepoint [17]	Weeks 0, 40 and 56 post-baseline
Secondary outcome [18]	Hip girth will be measured using a constant-tension measuring tape
Timepoint [18]	Weeks 0,8,16,24,32,40,56 post-baseline
Secondary outcome [19]	Insulin, from blood sample
Timepoint [19]	Weeks 0, 40 and 56 post-baseline

Eligibility

Key inclusion criteria	Men and women aged 50-70 years with body mass index (BMI) greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity (e.g. hypertension, dyslipidaemia or obstructive sleep apnoea)
Minimum age	50 Years
Maximum age	70 Years
Sex	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Known pregnancy, cardiovascular disease, diabetes, any history of pancreatitis; any history of multiple endocrine neoplasia (MEN) type 2 or medullary thyroid carcinoma; previous or planned bariatric surgery; any prior use of incretin-based therapies; use of non-incretin based anti-obesity or CV medications (e.g. statins, BP drugs) within 3 months of enrolment; and any other clinically significant illnesses (e.g. cancer, severe respiratory disease). Total cholesterol greater than 7.0 mmol/L, LDL greater than 4.0 mmol/L, eGFR less than 45 mL/min, HbA1c greater than 7.0% and/or evidence of significant liver disease. BP greater than 160/100 mmHg during the clinic visit.

Study design

Purpose of the study	Treatment
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	The allocation will be concealed via central randomisation by computer
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	Block randomisation will be used for participant allocation in order to ensure similar numbers and sex-matching of participants between groups. A bespoke 'ralloc' package will be used (Stata software, StataCorp, College Station, TX): blocks of 4 or 8 will be randomly selected and block randomisation will be stratified for gender.
Masking / blinding	Blinded (masking used)
Who is / are masked / blinded?	The people analysing the results/data
Intervention assignment	Parallel
Other design features	
Phase	Phase 3

Masking / blinding	Blinded (masking used)
Who is / are masked / blinded?	The people analysing the results/data
Intervention assignment	Parallel
Other design features	
Phase	Phase 3
Type of endpoint/s	Efficacy
Statistical methods / analysis	Data will be analysed on an intention to treat basis, by a professional statistician who is independent of the study. Data will be included for any participant who has received at least one session/dose of the intervention. For each of the pre-specified outcomes linear mixed models will be used to investigate the relationship between variables, exercise and time, while accounting for age, sex and BMI. A random intercept will be included in each model to account for the repeated nature of the data. The linear mixed model (LMM) is the preferred statistical test for repeated measures data sets. We will also conduct a completers analysis. For all analyses, interactions and main effects will be calculated.

Recruitment

Recruitment status	Recruiting

Date of first participant enrolment			
Anticipated	8/01/2024	**Actual**	6/03/2024

Date of last participant enrolment			
Anticipated		**Actual**	

Date of last data collection			
Anticipated		**Actual**	

Sample size					
Target	120	**Accrual to date**	60	**Final**	

Recruitment in Australia	
Recruitment state(s)	WA

Funding & Sponsors

Funding source category [1]	University
Name [1]	The University of Western Australia
Country [1]	Australia
Funding source category [2]	Commercial sector/Industry
Name [2]	Eli Lilly
Country [2]	Australia
Primary sponsor type	University
Name	The University of Western Australia
Country	Australia
Secondary sponsor category [1]	None
Name [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	The University of Western Australia Human Ethics Committee
Ethics committee address [1]	35 Stirling HighwayPerth WA 6009 Australia
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	
Approval date [1]	21/02/2023
Ethics approval number [1]	2022/ET000666

Summary

Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	
Approval date [1]	21/02/2023
Ethics approval number [1]	2022/ET000666

Summary

Brief summary	Obesity and physical inactivity are gateway conditions to prevalent and costly cardiovascular (CV) diseases including hypertension, type 2 diabetes, coronary artery disease, stroke and chronic kidney disease. Previous randomised trials have shown promising impacts on weight loss with the use of a self-administered drug called tirzepatide by modifying hormones released from the gastrointestinal tract, as a strategy for the management of obesity. However, an important issue in this and similar studies relates to the type of weight that was lost. In addition to losing fat, participants treated with tirzepatide can lose lean mass, including skeletal muscle. Maintenance of skeletal muscle mass and function are crucial to avoiding frailty, which is linked to cardiovascular diseases and mortality. Resistance exercise training (involving weight lifting type exercises) is known to increase skeletal muscle mass and function in humans, We hypothesise that: -The combination of tirzepatide and a resistance exercise intervention (targeted at reducing fat and increasing skeletal muscle mass), will optimise changes in body composition in our enrolled population, who are at high risk of future cardiovascular diseases. -Combining tirzepatide with exercise training will optimise vascular function and health in older men and women at high risk of future cardiovascular diseases. -Combining tirzepatide with exercise training will optimise heart function in older men and women at high risk of future cardiovascular diseases
Trial website	
Public notes	

Contacts

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Data sharing statement

Will the study consider sharing individual participant data?	No **No IPD sharing reason/comment:** IPD will not be shared, some aggregate data may be made available on reasonable request.

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Data sharing statement

Will the study consider sharing individual participant data?	No **No IPD sharing reason/comment:** IPD will not be shared, some aggregate data may be made available on reasonable request.

What supporting documents are/will be available?

No Supporting Document Provided

Results publications and other study-related documents

Documents added manually
No documents have been uploaded by study researchers.

Documents added automatically
No additional documents have been identified.

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Date of registration	May. 07, 2024
Last modified on	May. 07, 2024
Trial ID	jRCT1051240017

Scientific Title	A randomised, open-label trial to assess the effect of tirzepatide or semaglutide versus conventional tre atment on gut microbiota in Japanese patients with type 2 diabetes
Public Title	Osaka Metropolitan Diabetes & Obesity Trial 1 (OMDOT-1)

Contact for Scientific Queries	**Name**	Emoto Masanori
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Recruitment status	Recruiting

Anticipated date of first enrollment		May. 07, 2024
Actual date of first enrollment		
Target sample size		50
Study Type		Interventional
Study Design	**allocation**	randomized controlled trial
	masking	open(masking not used)
	control	no treatment control/standard of care control

Study Design	**allocation**	randomized controlled trial
	masking	open(masking not used)
	control	no treatment control/standard of care control
	assignment	parallel assignment
	purpose	other
Key inclusion & exclusion criteria	**Inclusion Criteria**	1. Patients with type 2 diabetes attending the facility during the trial period 2. Age >= 20 years and <80 year at the time of signing informed consent 3. Diagnosed with type 2 diabetes at least 180 days prior to screeing 4. Currently treated with metformin 5. If receiving oral antihyperglycemic drugs other than metformin and/or insulin, the type of drugs has not changed for at least 3 months (changes in dosage of the same drug are allowed). 6. HbA1c >= 7.0% and <10% at screening 7. BMI >= 23 kg/m2 at screening and beeing stable within 5% for the past 3 months 8. Able to carry out stable diet and exercise therapy during the research period
	Exclusion Criteria	1. History of type 1 diabetes 2. History of either chronic or acute pancreatitis 3. Uncontrolled and potentially unstable diabetic retinopathy or maculopathy at screening 4. Any history or evidence of chronic liver disease other than metabolic dysfunction-associated fatty liver disease (MAFLD) or AST and/or ALT >3x upper limit of normal range 5. Impaired renal function, defined as eGFR <30 mL/min/1.73 m2 at screening 6. Pregnant women, those who may be pregnant, or those who are breastfeeding 7. History of autoimmune disease, history of inflammatory bowell disease, history of organ transplantation or awaiting an organ transplant, or confirmed diagnosis of malignancy within 5 years prior to screening. 8. Treatment with any medication for the indication of obesity (mazindol) within 3 months before screening 9. Treatment with incretin-related anti-diabetes drugs other than DPP-4 inhibitors, such as GLP-1R agonists (liraglutide, dulaglutide, lixisenatide, exenatide, semaglutide), GLP-1R/GIPR dual agonist (tirzepatide), within 3 months before screening 10. Treatment with alpha-glucosidase inhibitors for type 2 diabetes wihtin 3 months before screening 11. Treatment with glucocorticoid 12. Treatment with any antibiotics or antiviral drugs within 1 month before the date of fecal collection 13. Patients who are judged to be ineligible to be the subject of this trial by the investigators, e.g., patients not expected to comply with the protocol requirements or not expected to complete the trial as scheduled
	Age Minimum	20age old over
	Age Maximum	80age old not
	Gender	Both
Health Condition(s) or Problem(s) Studied		Type 2 diabetes
Intervention(s)		arm A (control/non-treated group): current anti-diabetes treatment will continue for 16 weeks. arm B (tirzepatide group): tirzepatide will be administered subcutaneously (s.c.) at a starting dose of 2.5 mg/week for 4 weeks, then at a maintenance dose of 5.0 mg/week for 12 weeks. arm C: (semaglutide group): semaglutide will be administered s.c. at a starting dose of 0.25 mg/week for 4 weeks, then at a maintenance dose of 0.5~1.0 mg/week for 12 weeks.
Health Condition(s) Keyword		diabetes
Intervention(s) Keyword		
Health Condition(s) Code		D003924
Intervention(s) Code		
Primary Outcome(s)		Changes in the composition, gene functions and pathways of gut microbiota by metagenomic analysis at 16 week
Secondary Outcome(s)		1. Changes in the composition of gut microbiota over time (0, 4, 8, 12, 16 weeks) 2. Relationship between changes in clinical parameters (body weight, blood glucose/HbA1c, serum lipids, fatty liver index (FLI), urinary albumin-to-creatinine ratio (UACR), bone metabolism markers) and gut metabolites and changes in the composition/gene functions of gut microbiota

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Intervention(s) Code	
Primary Outcome(s)	Changes in the composition, gene functions and pathways of gut microbiota by metagenomic analysis at 16 week
Secondary Outcome(s)	1. Changes in the composition of gut microbiota over time (0, 4, 8, 12, 16 weeks) 2. Relationship between changes in clinical parameters (body weight, blood glucose/HbA1c, serum lipids, fatty liver index (FLI), urinary albumin-to-creatinine ratio (UACR), bone metabolism markers) and blood metabolites and changes in the composition/gene functions of gut microbiota 3. Differences in the gut microbiota composition/gene function changes between responders and non-responders for blood glucose/body weight after treatment.

Primary Sponsor	

Primary Sponsor	

Source of Monetary Support / Secondary Sponsor	
Secondary Sponsor	

Source of Monetary Support / Secondary Sponsor	
Secondary Sponsor	

Source of Monetary Support	
Secondary Sponsor	

Name of Certified Review Board	Ethical Committee of Osaka Metropolitan University Graduate School of Medicine
Address	Abeno Medics 6F, 1-2-7, Asahi-machi, abeno-ku, Osaka, 545-0051, Japan, Osaka
Telephone	+81-6-6645-3456
E-Mail	gr-a-knky-ethics@omu.ac.jp
Approval Status	Approval
Date of approval	April. 08, 2024

Plan to share IPD	Yes
Plan description	Information on individual research subjects is anonymized and managed in the cloud using the electric data collection management system "REDCap." This system also performs allocation to research subjects who are judged to be eligible. This system can only be accessed by a limited number of research personnel.

Secondary ID(s)	
Issuing Authority	

Countries of Recruitment（Except Japan）	none

Close

お問い合わせはこちら / For inquiries here webadmin_jrct@newpulse.co.jp
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個人情報保護方針はこちら

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画面トップへ

Tirzepatide (Mounjaro®) Benefit for EArly glycemic and weight managemenT in patients with type 2 diabetes vs. oral semaglutide (Rybelsus®) in real world setting – the T BEAT study (2023-12154)

First published: 26/07/2023 **Last updated:** 26/07/2023

EU PAS number: EUPAS106059

Study Planned

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Study identification

EU PAS number	EUPAS106059
Study ID	106060
Official title and acronym	Tirzepatide (Mounjaro®) Benefit for EArly glycemic and weight managemenT in patients with type 2 diabetes vs. oral semaglutide (Rybelsus®) in real world setting – the T BEAT study (2023-12154)
DARWIN EU® study	No
Study countries	Japan
Study description	Primary objective: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by HbA1c change from baseline after up to 12 months of treatment. Key secondary objective: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by body weight change and percent change from baseline after up to 12 months of treatment. Other secondary objectives: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by the proportion of participants achieving HbA1c targets (<5.7%, <6%, ≤6.5%, <7%) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by the proportion of participants who achieve weight loss targets (≥3%, ≥5%, ≥10%, ≥15%) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by metabolic parameters (waist circumference, blood pressure, serum lipids, liver function, and fasting plasma glucose FPG) after up to 12 months of treatment. - To compare the real-world effectiveness of

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compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by the proportion of participants who achieve weight loss targets (≥3%, ≥5%, ≥10%, ≥15%) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by metabolic parameters (waist circumference, blood pressure, serum lipids, liver function, and fasting plasma glucose FPG) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire change version DTSQc) after up to 12 months of treatment. - To compare the treatment persistency of tirzepatide vs. oral semaglutide over up to 12 months of treatment.

Study status	Planned

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024 **Last updated:** 01/02/2024

Institution

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Manaka Sato
Primary lead investigator

Study timelines

Date when funding contract was signed	Planned: 02/08/2023
Study start date	Planned: 15/12/2023
Date of final study report	Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Eli Lilly Japan K.K., Mitsubishi Tanabe Pharma Corporation

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Sources of funding

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Eli Lilly and Company

First published: 01/02/2024 **Last updated:** 01/02/2024

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Manaka Sato
Primary lead investigator

Study timelines

Date when funding contract was signed	Planned: 02/08/2023
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Date of final study report	Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Eli Lilly Japan K.K., Mitsubishi Tanabe Pharma Corporation

Regulatory

Was the study required by a regulatory body?	No
Is the study required by a Risk Management Plan (RMP)?	Not applicable

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Document title: Tirzepatide (Mounjaro®) Benefit for EArly glycemic and weight managemenT in patients with type 2 diabetes vs.☐ oral semaglutide (Rybelsus®) in real…
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Capture timestamp (UTC): Thu, 14 Aug 2025 18:39:28 GMT
Ex. 2050-012