

Obstructive Sleep Apnea & Diabetes weight management study

Research Centre: Flinders University

Location: Laffer Drive, Bedford Park SA 5042, Australia

Lead Researcher: Professor Danny Eckert

HREC: This study has been reviewed and approved by the Monash Human Research Ethics Committee

About the Study

Are you living with type 2 diabetes and struggling with obesity or being overweight? A new research study might offer hope. This study aims to explore a potential breakthrough treatment called Retatrutide. Designed to complement a healthy lifestyle, Retatrutide aims to assist adults in managing obesity, type 2 diabetes, and sleep apnoea. The study's core focus is to assess the effectiveness and safety of this new anti-obesity medication, offering a beacon of possibility for those navigating these interconnected health challenges.

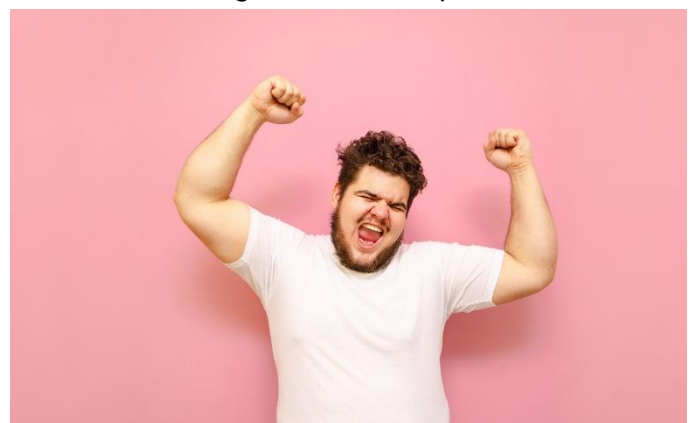


This research focuses on comparing Retatrutide with a placebo to see how it helps people manage both type 2 diabetes and weight issues. It's all about understanding if this new treatment can assist in tackling obesity while dealing with diabetes and sleep apnoea, significantly easing the burdens of chronic disease for both individuals and society as a whole. Your participation in this study could mark a turning point in the quest for more effective solutions, potentially lightening the load for those managing the complexities of these intertwined health conditions.

Interested? Click on this link to complete an online survey. This will add you to our research database. Mention in the notes that you are interested in the diabetes weight management study!

Why Participate?

- Participants may receive a new potential treatment for type 2 diabetes and obesity at no cost. The randomisation will have 3 groups on differing doses of the medication and 1 group on placebo (1:1:1:1). This means that there is a 75% chance of participants receiving the medication and a 25% chance of them receiving the placebo.
- Participants will receive lifestyle counselling by a dietician throughout the study.
- Participants will be compensated for their travel costs and reasonable out of pocket expenses.
- Participants may experience improvements in their sleep apnoea and type 2 diabetes symptoms. They may also experience improvements in how they manage their weight.



- Participants will be contributing valuable information that may benefit those with type 2 diabetes, obesity, and sleep apnoea in the future.
- Participants will be helping to advance medical research.

Your Rights

- If you decide to participate in the study and later feel that you no longer wish to be part of it, you can withdraw at any time.
- Any information that you provide will be kept strictly confidential, except as required by law.
- Qualified health professionals will monitor your health as it relates to the study.

Who Can Participate?

- Men and women aged 18 and above who are diagnosed with type 2 diabetes and obstructive sleep apnoea
- Must have obesity or be overweight, with a BMI of 27 or higher
- Must be willing and able to use effective contraception
- Must not be pregnant or planning to be pregnant within the following year
- Can be on CPAP therapy for sleep apnea or untreated
- Must not have had a prior or planned surgical treatment for obesity
- Must not be taking insulin regularly to treat diabetes
- Must not have had a diagnosis of cancer in the last 5 years (cervical cancer and skin cancer okay)
- Must not have had a significant cardiovascular event within 90 days prior to screening (Visit 1)
- Must not have a history of chronic or acute pancreatitis
- Must not have acute or chronic hepatitis
- Must not have known allergies or intolerance to GLP-1 receptor agonists, GIP/GLP-1 receptor agonist (e.g., Saxenda, Ozempic, Wegovy, Mounjaro)
- Must not have participated in another clinical study involving an investigational product within the past 90 days
- Must be able to attend 23 study visits and 2 overnight sleep studies at the research site over approximately 89 weeks

More Study Details

The study team will explain the research in its entirety but some details are:

- Participants will be asked to undergo a screening period lasting approximately 5 weeks with 2 planned visits and an overnight sleep study to assess study eligibility.
- Participants will be asked to experience a study treatment period spanning about 1 year and 6 months with 23 planned visits and 2 overnight sleep studies, receiving the study medication and self-administering weekly injections via a prefilled pen.
- Participants will have the option to participate in certain visits through telehealth (phone or video calls).

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