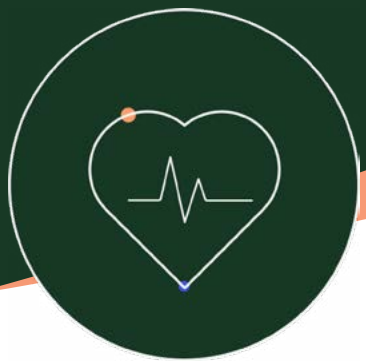
REDEFINE-3 Cardiovascular Disease Clinical trial



The cardiovascular safety and efficacy of cagrilintide 2.4 mg s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg s.c.) once-weekly in participants with established cardiovascular disease.

Study Rationale

To assess the cardiovascular (CV) safety and efficacy of the investigational product in individuals with established cardiovascular disease (CVD), with or without comorbidities such as obesity, overweight, T2D, and CKD.

Investigational Product

CagriSema, a fixed dose combination of cagrilintide and semaglutide. Both semaglutide, a GLP-1 receptor agonist, and cagrilintide, an amylin analogue, help regulate blood glucose levels. Earlier phase results indicate CagriSema reduces blood glucose more than semaglutide alone and so presents an exciting avenue for CV risk reduction.

Key Inclusion Criteria

- Aged 55 years or older.
- Have a body mass index (BMI) ≥ 25.0 kg/m2
- Have Type 2 diabetes with a HbA1c of between 6.5% and 10%
- Have established CVD as evidenced by at least one of the following:
  - Prior myocardial infarction.
  - Prior stroke (ischemic or haemorrhagic stroke).
  - Symptomatic peripheral arterial disease (PAD).

Key Exclusion Criteria

- Myocardial infarction, stroke, hospitalisation for unstable angina pectoris or transient ischaemic attack within 60 days before screening.
- Planned coronary, carotid or peripheral artery revascularisation known on the day of screening.
- Treatment with any GLP-1 RA or a medication with GLP-1 activity within 90 days before screening.
- Severe heart failure, renal disease, or regular dialysis (haemodialysis or peritoneal).

Study Schedule

This study is event (MACE) driven and expected to be up to 4.7 years (approximately 245 weeks). This includes:

- A screening period of up to 3 weeks.
- Randomisation into the placebo or study drug (CagriSema) group - each patient will have a one in two (50%) chance of receiving the study drug.
- A treatment period of up to 4.5 years.
- A 7-week follow-up period.

Each patient will be required to attend the study site up to 25 times and may withdraw from the study at any time.

Trial Sites

- Liverpool Hospital (NSW)
- Baker Heart and Diabetes Institute (VIC)
- Clinitrials (WA)
- One Clinical Research (WA)
- Royal Adelaide Hospital (SA)
- Royal Hobart Hospital (TAS)

More Information:

For more information about the study, please visit: www.evrima.com/active-trials
If you have any questions, please our Patient Experience team: patientexperience@evrima.com.au

Further Reading:

https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=21003&isClinicalTrial=True

NN9838-4942_GP Study Information Sheet V1_26NOV2023

clinical trial seeker