Efficacy, safety, and pharmacokinetics of cargrilinitide s.c. 2.4 mg in combination with semaglutide s.c. 2.4 mg (CagriSema) once weekly for weight management in children and adolescents with overweight or obesity

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- children who are 8 to <18 years old - history of at least one unsuccessful effort to lose sufficient body weight after participation in a structured lifestyle modification program (diet and exercise counselling) for at least 3 months - BMI requirements vary by age - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- treatment with any medication prescribed for obesity or weight management within 90 days before starting this study -Type 1 diabetes or monogenic diabetes - HbA1c greater than or equal to 6.5% if diagnosis of Type 2 diabetes has not been made - recurrent severe hypoglycaemic episodes within 1 year before starting the study - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: Cagrilintide, Drug: Placebo cagrilintide, Drug: Placebo semaglutide, Drug: Semaglutide
Conditions:
Children's Health
Keywords:
Clinics and Surgery Center (CSC), obesity, overweight

More Information

Description: This study will evaluate the efficacy, safety and pharmacokinetics of a combination drug called CagriSema, which is a combination of cagrilintide s.c. 2.4 mg and semaglutide s.c. 2.4 mg for the management of weight in children and adolescents with overweight or obesity. Participants in the study may receive study medication for up to 250 weeks.
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