

Naltrexone/Bupropion With or Without Very Low Calorie Ketogenic Diet for Weight Regain After Bariatric Surgery

NCT06881485

Status	RECRUITING
Phase	Not Applicable
Sponsor	Universitaire Ziekenhuizen KU Leuven
Enrollment	62 participants

Key Eligibility Criteria

Inclusion (6)

- Participants eligible for inclusion in this Trial must meet all of the following criteria:
- Voluntary written informed consent of the participant or their legally authorized representative has been obtained prior to any screening procedures
- Use of highly effective methods of birth control; defined as those that, alone or in combination, result in low failure rate (i.e., less than 1% per year) when used consistently and correctly; such as implants, injectables, combined oral contraceptives, some IUDs, true sexual abstinence (i.e. refraining from heterosexual intercourse during the entire period of risk associated with the Trial treatment(s)) or commitment to a vasectomised partner.
- Minimum 18 years of age at the time of Informed Consent signature
- Underwent bariatric surgery (RYGB or SG) with weight regain $\geq 10\%$ of nadir weight
- ... and 1 more (see full listing online)

Exclusion (11)

- Participants eligible for this Trial must not meet any of the following criteria:
- Participant has a history of type 2 diabetes mellitus (also drugs, HbA1c $> 6,5\%$ and FPG > 126 mg/dl)
- Ifemale who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using an adequate, highly effective contraceptive
- Participation in an interventional Trial with an investigational medicinal product (IMP) or device
- Not willing to sign informed consent
- ... and 6 more (see full listing online)

Locations (2 total)

UZ Leuven, Leuven, Vlaams-Brabant, Belgium
AZ Sint-Jan Brugge, Bruges, West-Vlaanderen, Belgium

<https://clinicaltrials.gov/study/NCT06881485>

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