

Effects of Cross-sex Hormone Therapy on Eating Behavior, Metabolism, Energy Balance and Cardiovascular System

NCT04838249

Status RECRUITING
Sponsor University of Leipzig
Enrollment 80 participants

Key Eligibility Criteria

Inclusion (3)

- transsexual patients undergoing cross-sex hormone therapy versus controls
- able to give informed consent, if <18 years from all legal guardians
- only for part B (patients will participate in all other study parts): weight stable (\pm 5%) for last 3 months, BMI \leq 30 kg/m²

Exclusion (6)

- severe medical impairments (e.g., uncontrolled cardiovascular disease, severe heart failure, uncontrolled hypertension, cerebral insult, active malign disease, etc.)
- self-initiated cross-sex hormone therapy before study start only for part B (patients will participate in all other study parts): Insufficiently controlled endocrine disorders (Cushing's disease, other uncontrolled pituitary disorders, uncontrolled hypothyroidism, hyperthyroidism, etc.)
- Chronic pulmonary disorders, including chronic obstructive pulmonary disease that would limit ability to follow the protocol (investigator judgment) and obstructive sleep apnea syndrome; only subjects with mild or exercise-induced asthma on no medications or on beta-adrenergic agonists only will be allowed to enter the study (provided use of these agents is not required for 1 week before)
- Diagnosed gastrointestinal diseases, including inflammatory bowel diseases (e.g. Crohn's disease and ulcerative colitis), malabsorption syndromes (e.g. celiac disease), gastric ulcer (active); only subjects with gastro-esophageal reflux will be allowed to enter the study entry).
- History of HIV infection or ongoing chronic infection (such as tuberculosis)
- ... and 1 more (see full listing online)

Locations (1 total)

Helmholtz Institute for Metabolic, Obesity and Vascular Research, Leipzig, Saxony, Germany

<https://clinicaltrials.gov/study/NCT04838249>

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