

Investigating Gender and Sex Differences in Immune Responses Through Vaccination of Transgender and Cisgender Persons

NCT06832514

Status	RECRUITING
Phase	Phase 4
Sponsor	University Ghent
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (8)

- Written signed informed consent form (ICF) obtained before any study-related activities.
- Participants aged between, and including, 18 and 50 years of age at the time of signing the ICF which equals with the time of the first study intervention.
- Participants who are considered to be in good general health as determined by the investigator by medical evaluation including medical history and physical examination at enrollment.
- Participants with a BMI within the range 18.5 to 35 kg/m² inclusive at screening.
- POCBP (18-50 years of age) who are not pregnant or breastfeeding or planning to become pregnant during the clinical study.
- ... and 3 more (see full listing online)

Exclusion (24)

- Current or previous, confirmed or suspected disease caused by N. meningitidis and N. gonorrhoea.
- Household contact with and/or intimate exposure (e.g. sexual or saliva contact) to an individual with laboratory confirmed N. meningitidis infection during life.
- Transgender persons in a diagnostic phase (no hormonal intervention) or undergoing treatment based on the suppression of endogenous hormones (e.g. gonadotropin releasing hormone analogues).
- Current or previous infection with hepatitis B, hepatitis C or human immunodeficiency virus (HIV) as determined by anamnesis and medical history.
- Past or current confirmed or suspected immune-suppressive or immune-deficient condition, at the discretion of the investigator, including but not limited to blood, endocrine, hepatic, muscular, nervous system or skin autoimmune disorders, lupus erythematosus and associated conditions or disorders (e.g. rheumatoid arthritis, scleroderma) or immunodeficiency syndromes (including, but not limited to: acquired immunodeficiency syndromes and primary immunodeficiency syndromes).
- ... and 19 more (see full listing online)

Locations (1 total)

CEVAC, University Hospital Ghent, Belgium, Ghent, Belgium