Test-retest Study With [18F]FBB in Cardiac Amyloidosis

NCT06790394

Status	RECRUITING
Phase	Phase 1
Sponsor	Life Molecular Imaging GmbH
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (13)

- Males and females aged e40 years
- Able to understand, sign, and date written informed consent
- Written informed consent must be obtained before any assessment is performed
- Female subjects must be documented by medical records or physician's note to be either surgically sterile (by means of hysterectomy, bilateral salpingectomy or bilateral oophorectomy) or post-menopausal for at least 1 year (no menses for 12 months without an alternative medical cause). If they are of child-bearing potential, they must commit to use of a highly effective contraceptive measure for one week after the PET scan (including combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable or implantable), intrauterine device, intrauterine hormone-releasing system, bilateral tubal occlusion, vasectomised partner or sexual abstinence)
- Male subjects and their partners of childbearing potential must commit to the use of a highly effective method of contraception for a minimum of 90 days following each PET scan (including, for female partners of childbearing potential, combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable or implantable), intrauterine device, intrauterine hormone-releasing system, bilateral tubal occlusion, male subjects with vasectomy or sexual abstinence)

... and 8 more (see full listing online)

Exclusion (10)

- Subject has received, in the last 3 months, or currently receives amyloid targeting monoclonal antibody therapy.
- Any known allergic reactions or hypersensitivity towards any compound of the study drug
- Hemoglobin value \< 10 g/dL
- Severe hepatic impairment (AST or ALT \>5 x ULN; bilirubin \>3 x ULN)
- Subject receives hemodialysis or peritoneal dialysis

... and 5 more (see full listing online)

Locations (2 total)

Royal Free Hospital, London, United Kingdom
King's College London, London, United Kingdom