

Title: Phase II study to evaluate the clinical potential of ⁶⁸GaNOTA-Anti-MMR-VHH2 for in vivo imaging of MMR-expressing Macrophages by means of Positron Emission Tomography (PET) in oncological lesions, cardiovascular atherosclerosis, syndrome with abnormal immune activation and sarcoidosis.

EudraCT number: 2020-002483-31

Protocol name: UZBRU_VHH2_2

Trial prematurely ended. Not all planned participants were included in the trial.

This single centre, open-label, non-randomized, phase II study evaluated the clinical potential of ⁶⁸GaNOTA-Anti-MMR-VHH2 for in vivo imaging of MMR-expressing Macrophages by means of Positron Emission Tomography (PET) in oncological lesions, cardiovascular atherosclerosis, syndrome with abnormal immune activation and sarcoidosis.

The study was divided in 7 cohorts. In total, 29 patients were included.

- (1) Patients with a malignancy of the head and neck (3 patients)
- (2) patients who received immune checkpoint inhibition treatment for a solid malignancy (0 patients)
- (3) patients who were planned for a carotid endarterectomy (10 patients)
- (4) patients with a lymphoma (9 patients)
- (5) patients with HLH (2 patients)
- (6) patients with probable cardiac sarcoidosis (4 patients)
- (7) patients with biopsy proven sarcoidosis(1 patient).

One adverse event was reported. This patient experienced abdominal pain at the place where the lymphoma was punctured (mild). The patient recovered and this AE was unlikely to be related to the study drug.

A paper reporting these data is currently being prepared. The paper will be submitted in the course of 2026.

On behalf of UZ Brussels.

Department of nuclear medicine.