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MULTIDISCIPLINARY CAR-T TEAM

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What was done?

A multidisciplinary team (CAR-T team) was constituted for the management of CAR-T therapies (Chimeric Antigen Receptor T). The pharmacist was included in the team for the planning and organizational phase of the process.

Why was it done?

CAR-T cell therapies are a new advanced type of personalized immunotherapy against cancer. CAR-T therapies production and administration process consist of multiple stages: considering the complexity of the procedure and the observance of specific schedules, these therapies should be administered in highly specialised centers complying with specific organizational requirements, with disposal of an adequate multidisciplinary team.

How was it done?

The pharmacist is responsible for the approval of the physician's prescription, the Lymphodepleting Chemotherapy (LC) preparation according to Good Manufacturing Practice (GMP), the LC distribution on scheduled time, the making available of treatments for supporting patient until CAR-T infusion and treatments after infusion for management of adverse events. At the arrival of CAR-T product, the pharmacist is responsible for the check and release in good conditions.

	Governance and guidelines	Process and procedures	Technologic systems and infrastuctures	Internal team
Patient evaluation and selection	National facility accreditation and reimbursement process	Car-t therapy approval application process	Organ function tests, blood tests	**Hematologists with Car-T experience and critical experts**
T-cell extraction and preparation	National T-cell collection standards and contract manufacturers	Autologous cellular extraction, transport and shipping procedures	Leukapheresis device for patient cells extraction	**Staff T-cell collection**
Genetic engineering and expansion		YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion KYMRIAH™ (tisagenlecleucel) Suspension for IV infusion	used in our center as third line for the EU registered indication of diffuse large B-cell lymphoma	
Conditioning therapy and infusion	Protocol for product handling, receipt, thawing, infusion. Hospital pharmacy audit	Process of traceability, identification of product. lymphodepleting chemotherapy (LC)*	Pharmacy infrastucture to support and store the product	**Hospital Pharmacists trained for unpackaging, QC and storage. Multidisciplinary team for product infusion**
Post-treatment and recovery	Regulatory post-treatments requirement	Toxicity and adverse events monitoring and management	Remote monitoring facilities, post-infusion accomodation and reporting systems	**Treatment response assessment criteria. Physician follow-up**

* The LC protocols foresee the administration of cyclophosphamide and fludarabine on the 5th, 4th and 3rd day before the CAR-T infusion, and are defined on the base of the summary-of-product-characteristics. The medications are provided locally and refunded by national health system.

What has been achieved?

In our center 12 patients were treated with axicabtagene ciloleucel (8 with compassionate use and then 4 with commercial use). The pharmacists presence in the multidisciplinary team was advantageous because, through validation of the therapies and verification of dosages, they guarantee further security to the patients. The high-tech automated centralization and computerization of chemotherapies ensured quality and safety of the preparations.

What next?

The realization of defined paths and codified proceedings, the respect of fundamental timings for the success of the process and the chemotherapy preparation centralization could lead to increased investment, decisive for obtaining a high quality product and process level. The experience, now limited to hematology, could be used for future CAR-T applications.

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https://www.eahp.eu/gpis/multidisciplinary-car-t-team