

5PSQ-065

SECTION 5: PATIENT SAFETY  
AND QUALITY ASSURANCE

# BE A HUMAN, NOT A CASE REPORT: HOSPITAL PHARMACISTS MAKE THE DIFFERENCE

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## Background and importance

The hospital pharmacy of our Health Institute is eligible to carry out phase 1 study till 2017. In July 2021 a multidisciplinary team, which includes pharmacists, approved the choice to enlist a 61-year-old man of 70 kg affected by colon cancer fourth stage, inoperable, with failure of all drug therapies and without therapeutic treatment.

## Aim and objectives

The aim of our work was to create a personalized pharmacological therapy in order to improve patient's life expectancy, minimizing side effects.

## Material and methods

Evaluation and creation of a custom pharmacological protocol, with continuous monitoring of patient's vital parameters, before, during and after drug administration. The calculated dose was 5mg/kg. Pharmacists were involved also in monitoring of adverse drug reactions, scheduling periodical patient interview and participating in the review of therapy with clinicians. Specifically 24 h from the first injection; 7 and 15 days after drug administration.



## Results

Reduction in the volume of morphological lesions after a month from first infusion, observed by computed tomography, according to response evaluation criteria in solid tumors (RECIST 1.1): supraclavicular lesion on the left (cm 1.6 vs cm 2.7); paratracheal formation (cm 1.6 vs 1.4); formation of the aorta-pulmonary window (cm 1.6 vs 1.8); decreased hepatic formation (cm 4.6 vs cm 5.1). After nine months from first administration, we observed that reduction of morphological volume lesions remains constant. No adverse reactions were presented in the whole observational period. In addition, the patient interviewed reports less fatigue and increased mobility.

## Conclusion and Relevance

Phase 1 study (eudract 2017-002615-33) involves the use of LNA- i-miR-221, a new molecule synthesized to inhibit mir-221, which may be responsible for cellular dysfunction attributable to increased proliferation and inhibition of apoptosis, which has always been all markers of cancer. Single drug vial contains 35 mg. The calculated dose was 350 mg, reconstituted with 20 ml NaCl, infused in total volume of 100 ml for 30 minutes. Therapy personalization and interdisciplinary collaboration proved to be a success in ensuring help and limiting adverse effects.



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