Nanomedicine upscaling for early clinical phases of multimodal cancer therapy

Sprawozdania

Informacje na temat projektu

NoCanTher

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Podsumowanie kontekstu i ogólnych celów projektu

The NoCanTher consortium planned to test in humans a new therapy for pancreatic cancer based on magnetic nanoparticles, which has a very bad prognosis, with a survival rate after 5 years (< 5%) unchanged over the last 30 years, despite tremendous efforts at the preclinical and clinical stage.

Worldwide in 2012 there were 338,000 new cases of pancreatic cancer and 331,000 associated deaths. Currently, surgery is the one curative treatment for PDAC (Pancreatic Ductal AdenoCarcinoma, a type of pancreatic cancer) but only a minority of patients present with potentially operable disease (10–20%). Therefore, there is an urgent need to develop effective treatments for this disease, and those based on nanotechnology might solve some of the problems faced with this disease.

Our approach is based on magnetic hyperthermia, where magnetic nanoparticles placed in the tumor are exposed to an alternating magnetic field (AMF) leading to an increase of the temperature of the particles and therefore the tumoral area.
Thus, to test this approach in humans, we needed to meet the following objectives:

SO1- Up-scaling under Certified Conditions.
The objective was to provide magnetic nanoparticles with the required properties for the therapeutic system exploited in this project, based on magnetic hyperthermia. These particles should be produced in a scalable manner and with the required certification for a clinical study.

SO2 - Preclinical assessment for the elaboration of the IMDD.
This objective aimed to collect information on the nanoparticles regarding their efficacy and safety. Thus, the particles were studied in different animal models, biodistribution and toxicity studies, including the required regulatory toxicity studies. All this information was used to prepare a Dossier for the clinical study.

SO3 - Clinical Study implementation.

With Clinical Study Authorisation, we started the clinical study using our therapeutic approach (nanoparticles and AMF producing device required to induce hyperthermia with the nanoparticles). The protocol for this study was designed based on the efficacy and toxicity results obtained in the preclinical assessment.

Conclusion:

The project has maintained its course of the final period on track for the impact envisioned at the beginning of the project. The progress towards the Specific Objectives has been clear with SO1 and SO2 have been met and the positive approval of the clinical study as part of SO3, the news of the first patient’s recruitment demonstrates the successful achievement of the project.

Although the clinical study is ongoing due to aforementioned reason our focus as a group is to maintain the momentum of the project outputs and complete the study. This will bring high visibility to

the project outcomes and is already having a great impact in the society. In this regard, we want to highlight that during the development of the NTT System, we have had several meetings with Notified Bodies and the Spanish Drug Agency, to explain the approach, and we finally submitted the request for the study. Also at the hospitals we have met with the clinicians to discuss the technology and the ethical issues involved in the study. Similarly, we have had several activities with the Spanish Cancer Society, the Spanish Nanomedicine platform, politicians and the general public to explain the project and the advantages of using nanotechnology-based approaches to treat diseases.

We are convinced that these actions will ease the introduction of novel approaches based on nanotechnology. Therefore, besides the inherent impact of the NoCanTher project due to the development of a treatment of pancreatic cancer, our activities will have a multiplier effect on the society, which now understands better and supports more the development of novel therapeutic strategies, as this one funded by the EC. Besides the impact in the society in these terms, we believe that products/science developed (NTT agents, generators, magnetometer, synthetic and evaluation procedures, toxicity studies) is of utmost importance to European companies and scientific institutions to be competitive in the area of Health where new materials are involved.

The NoCanTher consortium counts on the involvement of 11 institutions from three different sectors (Academia, industrial, clinical) and five different countries (Spain, France, Germany, UK, and Ireland).

Prace wykonane od początku projektu do końca okresu sprawozdawczego oraz najważniejsze dotychczasowe rezultaty

Since the beginning of the Project the consortium has been focused on the large-scale production and assessment of nanoparticles. These must be prepared not only on a large scale but importantly under certified conditions. A production line has been created specifically dedicated to this and has involved the work of two Industrial partners from two different countries. Knowledge has been transferred assisted by the Academic partners using their expertise of these types of therapeutics –a truly cross-sectoral approach. For the other part of the therapy, an AMF generator has been developed , which must fulfil the strict regulation to be used in the clinic, again the consortium has worked together to achieve these goals. Thus, the nanoparticles are produced under the required regulation and AMF generators are ready to be delivered to the clinical sites –a huge milestone for the Project.

Meanwhile, the preclinical teams across 3 sites have been collecting information on the nanoparticles regarding their efficacy and safety. A preclinical version of the AMF generator has been used to assist the translation to the clinical setting. Thus, the efficacy of the approach (magnetic nanoparticles + AMF generator) have been studied in different animal models, including the biodistribution and toxicity studies of the nanoparticles. What is more, the required regulatory toxicity studies have been also carried out. The safety of the nanoparticles and device has also been thoroughly studied, with work towards the industrial sustainability of the process.

All of this information together with the certified production methods has allowed us to apply for the

clinical trial authorisation, which has been recently granted.

In March 2022, the NoCanTher clinical study accepted its first patient with locally advanced pancreatic cancer who is now receiving treatment with this novel strategy at Vall d'Hebron University Hospital. This pilot study promises potential new therapeutic avenues for patients with locally advanced pancreatic cancer, for whom there are no other treatment options available except chemotherapy.

To spread the word of what the consortium has achieved in the NoCanTher project, the consortium has been represented at multiple events across Europe, communicating and disseminating the result and aims of the project, reaching out to the general public, researchers, clinicians and stakeholders. The first patient recruitment and their treatment will help maximise impact of this successful project

Innowacyjność oraz oczekiwany potencjalny wpływ (w tym dotychczasowe znaczenie społeczno-gospodarcze i szersze implikacje społeczne projektu)

This approach is quite novel and the combination of the two medical devices developed in the consortium have not been employed for the treatment of pancreatic cancer. The challenges ahead are diverse, but we expect to report an effective therapy against pancreatic cancer that can be implemented in hospitals at a moderate cost. Thus, we hope that citizens along Europe will benefit from this innovative therapeutic approach, improving the survival rate and reducing the pain associated with the disease.

Conosrtium Picture 2018

The first patient undergoing treatment

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