Plan Overview

A Data Management Plan created using DMPonline

Title: Smart thermosensitive systems based on hydrogels and biocompatible nanomaterials

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Project abstract:

Osteoarthritis (OA) is the most common degenerative joint disease worldwide, characterized by biochemical, morphological and molecular changes that cause pain and inflammation in the synovial membrane of the joints, leading to the progressive destruction of articular cartilage (AC). The pathogenesis of OA is influenced by various genetic and environmental factors. However, the molecular mechanisms driving OA progression remain poorly understood, and no effective strategies currently exist to prevent OA or halt the progression of damaged cartilage. Thus, to identify compounds that can block the Ihh pathway and its signalling cascade represents a promising strategy to prevent or treat OA. In this sense, the main objectives of this project are: to develop a controlled-release multifunctional injectable IA system of therapeutic molecules that target the suppression or inhibition of the Ihh pathway and to establish 3D organoid models with samples from patients with OA pathologies to replace *in vivo* assays with organoid models. This project is based on the hypothesis that the proposed delivery systems will be capable of releasing compounds in a targeted and controlled manner, that not only alleviate the symptoms of OA, but also act on the underlying molecular bases of the pathology restoring joint functionality. The use of POEGMA as a thermosensitive material in cartilage degeneration studies is unprecedented, as well as 3D *in vitro* organoid models from OA patients' cells have not yet been studied, which would constitute one of the innovations of this project, since in inflammation processes there is an increase in local temperature that would produce the stimulated release of therapeutic compounds.

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Copyright information:

Smart thermosensitive systems based on hydrogels and biocompatible nanomaterials

Data Collection

What data will you collect or create?

During the execution of the project, we will collect important data, including: 1- textual results (document in doc format) regarding the electrospinning parameters of the nanofibers; 2- chemical and microscopic characterizations of the nanofibers and nanogels (these data will be numerical in txt format); 3- numerical data (spreadsheets in xls format) on the percentages of controlled release of therapeutic molecules; 4- concentration range for performing daidzein tests (numerical data, database in xls format); 5- histological and molecular biology results will be images in jpg format. All collected data must have a maximum volume of 10 MB.

How will the data be collected or created?

To generate the data, we will perform: synthesis of thermoresponsive smart nanohydrogels, fabrication of nanofibers, controlled release tests, in vitro cytotoxicity tests in 2D and 3D models and preclinical evaluation of our injectable hydrogel systems. The methodologies that will be used will be laboratory notebooks and the Origin software. There will be no restriction on the data obtained in this project. It is very necessary to generate data in at least triplicates, to ensure the reproducibility of our data since the research is of an innovative nature and there are few data reported to date.

Documentation and Metadata

What documentation and metadata will accompany the data?

The data generated in this project will be accompanied by descriptive metadata such as “documents” and “images”. Authors and article titles will be saved in the Mendeley database, organized in folders identified with their names. On my computer, the results folders will be identified with the years/test name/date.

Ethics and Legal Compliance

How will you manage any ethical issues?

Data will be reported responsibly, whenever it is necessary to present them, no empirical data will be omitted, deleted or modified. All confidential data ethics will be maintained until publication. Regarding patient and donor data, these will be pseudonymized and only the surgeon treating the

patients will have access to them and knowledge of the pseudonyms. On the other hand, the ethical and legal aspects of this project are applicable in WPs 2 and 3. In WP2, the use of tissue samples obtained from patients is required. In this sense, the protection of the safety of the study subjects, their well-being and their rights will be guaranteed, as stated in the favorable evaluation of CEICA (PI20/429), in accordance with the Data Protection Law in force in Spain. Patients will sign an informed consent that Dr. García-Álvarez will provide them with prior to surgery. In this document, the PI agrees to provide patients with information about the results obtained from their samples upon request. In fact, the PI and the research team will not know the personal data of the patients (the samples will be collected with a numerical code), except for Dr. García-Álvarez, who is the surgeon of these patients. Patients will be adequately informed about the voluntary nature of their participation in this research, the observational nature and objectives of the research in which they are participating, as well as about the protection of personal data.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The data derived from this proposal will be published in Open Access, which allows maximizing the dissemination of the results obtained, avoiding economic or legal implications for the general public to access them.

Storage and Backup

How will the data be stored and backed up during the research?

The data generated during the research for this project will be saved in the cloud and on hard drives. Backups will be made weekly (every Friday). In the event of a computer incident on the notebook, there will be no significant loss of data, as they will be stored in two different locations.

How will you manage access and security?

Access to the digital results will be managed through passwords, known only to the principal investigator and the two supervisors.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data generated is equally important. All data will be stored, preserved and available for consultation even after the end of the project. The data derived from the proposal will be published in Open Access and stored in an open access repository (Zenodo), separated and identified by folders related to the experimental results. Both myself and my supervisors Dr. Arruebo and Dr. Mendoza will keep a copy of the data on their computer and/or external hard drive. Access to the data stored in the repository will be allowed by password only to researchers participating in the project.

What is the long-term preservation plan for the dataset?

The data derived from the proposal will be published in Open Access and stored in an open access repository (Zenodo), separated and identified by folders related to the experimental results.

Data Sharing

How will you share the data?

The data will be shared through publications of scientific articles, presentations at national and international conferences, seminars and workshops. In addition, they will be shared in the reliable data repository: Zenodo of IISA, which will be partially available from the first year of the project. The full release of all data will be after the 5 articles scheduled to be written are accepted in high-impact journals.

Are any restrictions on data sharing required?

Once the data is shared, it will be available to all researchers with a scientific interest.

Responsibilities and Resources

Who will be responsible for data management?

The principal investigator will be primarily responsible for management activities, data custody (data capture, data production, data quality, storage, archiving and data exchanges.

What resources will you require to deliver your plan?

In this first version of the Data Management Plan, we will not need any financial resources to deliver the data.