iDentgel: Immune-modulated dental pulp regeneration through dual-cure injectable nanocomposite hydrogel

A Data Management Plan created using DMPonline.be

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Project abstract:

Oral health is a key factor in overall health and well-being. Oral health problems can lead to severe infections, pain, and irreversible dental tissue damage. Apart from conventional treatment options for oral rehabilitation, regenerative dental procedures have been recently introduced as potentially valuable treatment options. Overall, approaches for dental tissue engineering and regenerative medicine (TERM) may be either cell-free or cell-based, meanwhile opting for various types of drug delivery and applying immune-modulation to ensure an improved outcome. In this context, chemokine SDF-1/CXCL12 has shown great potential in dental pulp regeneration. However, the use of chemokines in TERM is challenging because of the short half-lives, rapid diffusion, appropriate dosing, sensitivity to proteases, and direct deactivation in an inflammatory environment, such as the oral cavity. The present project introduces a novel approach to introduce polymeric nanoparticles as a delivery system to overcome chemokine drawbacks, promoting sustained release and protection against proteolytic degradation. The aim of the present project is to develop a dual-cure, SDF-1/CXCL12-loaded nanocomposite hydrogel to promote cell attachment, migration, growth, and cell differentiation serving dental pulp regeneration.

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Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

During this project, new data will be generated. No personal data will be involved. For material characterizations and *in vitro* studies, the following data will be generated: dynamic light scattering measurements, scanning electron and transmission electron microscopy images, confocal imaging, ELISA, SDS-PAGE, DNA quantification, alkaline phosphatase activity and quantitative polymerase chain reaction.
For *ex vivo* studies, the following data will be generated: proteomics analyses, nano-computed tomography images, immunohistochemistry, and histology images.
Digital images will be saved as .tiff files with an estimated volume of 1 TB. All data extracted will be initially collected in a variety of file formats, being mainly .xlsx, .docx, etc.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

The data will be preserved under the responsibility of Prof. Reinhilde Jacobs and Prof. Arn Mignon. During research, data will be stored in the designated OMFS-IMPATH large storage server, as part of the Gbiomed controlled large storage data servers of KU Leuven, that are equipped with back-up capacities. Furthermore, data will be stored at shared OneDrive of the research group which get a back-up regularly as well. Lab notebooks will be used to store information related to experimental protocols and will be kept in a central location at all times and will be stored for up to 20 years. After research, data will be preserved during 20 years using the same resources.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

As the research will involve synthesis and processing procedures, which will be of the utmost importance for the research group for other projects as well, these protocols will result in Standard Operating Procedures (SOPs). These SOPs will be used and shared in the research group long after the period of the project and therefore lab notebooks will be kept for up to 20 years.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

NA

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

NA

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FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Microscopy images	Experimental immunohistochemistry, histology and Immunofluorescence images taken in brightfield or confocal microscopes	Generate new data	Digital and physical	Experimental	.tiff .jpeg	<100GB	Tissue slides will be stored at room temperature, and they will take approximately 4 boxes.
Material characterization experiments	Characterization experiments to determine morphology/composition of synthesized materials	Generate new data	Digital	Experimental	.xsls .docx .pdf	<100GB	
Biological experiments	Experiments performed to examine the cytotoxicity and efficacy of the product	Generate new data	Digital	Experimental	.xsls .docx .pdf	<100GB	
Whole tooth model	Proof of concept of the product in an ex vivo whole tooth model	Generate new data	Digital and Physical	Experimental	.xsls .docx	<100GB	The extracted teeth will be processed on the day self, so there is no need for extra storage. The further analysis is histology, and the storage is explained above.

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

NA

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

For the ex vivo tooth model, human widsom molars will be used. Ethical approval obtained by Commission for Medical Ethics of KU Leuven (file number S54254).

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- No

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

The outcome of the whole tooth model has potential to be patented.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- Yes

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

WP1, WP2, WP3: All protocols and structured notes will be available either as part of a publication or in the L-Drive of the research group under the corresponding folder to the project (word, xl, and .pdf files).
These documents shall describe detailed protocols, descriptions of materials/instrumental parameters as well as the analysis/parameters used on the raw data.
What concerns the statistical analysis, all coding sheets, data comparisons, and statistical methods will be saved in these corresponding folders

as well.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

There are no standards for metadata for most of the experiments carried out in this project. For this reason, all relevant experimental information for reproducibility will be
collected and stored with the data: cell lines, culture conditions, instrument settings, experimental conditions (time points, control groups) and analysis software information will be included.

3. Data storage & back-up during the research project

Where will the data be stored?

1. All experimental data will be stored in an electronic lab book with the chronological reporting of all related experiments. Results will be reported in electronic books that include a cross reference to the electronic lab book. All data, experimental lab books and reports are stored electronically on the personal KU Leuven One Drive for daily back-up and they are moved to the Large Volume Storage of the KU Leuven ICTS on a monthly basis. Larger and RAW data files (SEM/TEM images) are directly stored on the Large Volume Storage of the KU Leuven ICTS, designated for the OMFS-IMPATH research group.
2. The physical data will be stored in a closed storage cabinet in a locked office at the University Hospital Leuven, St. Raphael, 3000 Leuven.

How will the data be backed up?

Daily back-up of newly generated data is guaranteed with the KU Leuven One Drive service, while for the Large Volume Storage the general ICT backup Policy is applied.
For non-digital data, digital copies of the files will be made on a monthly basis and stored in the L-Drive.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

The OneDrive has a limitation in storage capacity (2TB) which will be sufficient for the electronic lab notebooks, small datasets and experiment reports generated in this project. The reserach groups provides sufficient data storage for all larger data files in the Large Volume Storage of the KU Leuven ICTS. Since the data are stored on KU Leuven servers, and these drives are expandable in blocks, the backup capacity is technically not an issue.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Data stored in the KU Leuven One Drive is not accessible by any other person except the researcher. All data will be stored in the university's secure environment for private data in a certified and GDPR compliant cloud platform.. Data files in the Large Volume Storage of the KU Leuven ICTS are only accessible by lab members via a two-step authentication system. When making the decision to dispose of the research data and materials, the data manager will consider professional standards, legal requirements, and contractual arrangements.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

The KU Leuven OneDrive comes without charge, and will be enough for storing data/lab notebooks and reports for the entire duration of the project.

The cost of the storage of 5TB of data for 1 year on KU Leuven L-Drive server is €569.2, which corresponds to the minimum possible to pay. The total amount will then be €2277 during the 4 years of the project. The cost will be covered by existing lab grants.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

All protocols created during the project will be kept for 20 years. This is due to the fact that they are SOPs, that will be used for future research as well.
The data generated will be kept for at least 20 years as well, seen the potential for patenting the outcomes.

Where will these data be archived (stored and curated for the long-term)?

Data relevant to the research will be securely stored for 10 years at the dedicated and protected OMFS-IMPATH server location of the Biomedical Sciences group of the KU Leuven (L-Drive). After 10 years the researchers will decide whether it is necessary to store the data for a longer time. If it is necessary to keep the data, a reminder date will be set at which the researchers will again decide whether the data still need to be kept. When further storage is no longer necessary the data will be deleted.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The cost of the storage of 5TB of data for 1 year on KU Leuven L-Drive server is €569.2,
which corresponds to the minimum possible to pay. Thus, for 5 years, it would be €2845.
However, since the expected data for this project is 1TB, we anticipate being able to share these costs with other lab projects that also need to be stored for the long term. These costs will be met by existing lab grants.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in an Open Access repository

NA

If access is restricted, please specify who will be able to access the data and under what conditions.

NA

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Intellectual Property Rights

Before publications are made and data is disseminated, LRD office of KU Leuven will be contacted to control the IPR.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

The PhD booklet with the research content will be shared on the research group website and stored in the KBR depot. The published articles are available online.

When will the data be made available?

Data will only be made available to other researchers after the publication of the research
results, after consulting with the KU Leuven LRD office to ensure no IPR are being exceeded.

Which data usage licenses are you going to provide? If none, please explain why.

Creative Commons Attribution-ShareAlike (CC-BY-SA). This is because the data is patentable.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

DOI will be provided upon acceptance for publication of the related research papers.

What are the expected costs for data sharing? How will these costs be covered?

Since this considers smaller datasets, the repository will cover for it.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

Una Ivković will be responsible for these tasks until the time due on her contract. Prof. dr. Reinhilde Jacobs will be responsible afterward to ensure data preservation and reuse.

Who will manage data storage and backup during the research project?

Una Ivković will be responsible for these tasks until the time due on her contract. Prof. dr. Reinhilde Jacobs will be responsible afterward to ensure data preservation and reuse.

Who will manage data preservation and sharing?

Una Ivković will be responsible for these tasks until the time due on her contract. Prof. dr. Reinhilde Jacobs will be responsible afterward to ensure data preservation and reuse.

Who will update and implement this DMP?

Una Ivković bears the end responsibility of updating & implementing this DMP

iDentgel: Immune-modulated dental pulp regeneration through dual-cure injectable nanocomposite hydrogel GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

iDentgel: Immune-modulated dental pulp regeneration through dual-cure injectable nanocomposite hydrogel DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable