Plan Overview

A Data Management Plan created using DMPonline.be

Title: Concomitant Reversal of adrenal insufficiency and muscle weakness to enhance recovery from prolonged critical illness

Creator: Lies Langouche

Principal Investigator: n.n.

Data Manager: Lies Langouche

Project Administrator: Lies Langouche

Affiliation: KU Leuven (KUL)

Funder: European Research Council (ERC)

Template: ERC DMP +

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Project abstract:

Sepsis, complicated surgery or extensive trauma cause hyperinflammation-induced critical illness which requires vital organ support in an intensive care unit (ICU) in order to avoid imminent death. Although modern intensive care has reduced mortality, a large number of survivors continue to require such supportive care in the ICU sometimes for weeks or months. Once in this prolonged phase, typical ICU-acquired morbidities such as lingering organ failure, muscle wasting and weakness and vasopressor- and ventilator-dependency become the main drivers of poor short- and long-term outcome irrespective of the initial diagnosis upon admission. Research from our group has focused on two of these unresolved problems, namely ICU-acquired muscle weakness and ICU-acquired adrenal insufficiency, for which there is either no treatment or treatment has deleterious off-target effects that may fuel a vicious circle impairing short- and long-term recovery. Today, intensivists see these conditions as two separate pathophysiological entities, an assumption we think is false. We hypothesize that ICU-acquired adrenal insufficiency shares upstream underlying mechanisms with ICU-acquired muscle weakness, pathways that are currently unexplored and that can be manipulated with the potential to reverse both problems together. We will test this hypothesis via an experimental and a clinical track. The proposal starts from a novel, controversial idea, developed via experiments in a unique, clinically relevant and validated mouse model of sepsis-induced critical illness and via the study of human patients, and aims to close the loop with a proof-of-concept randomized controlled trial. Our ambition is to identify and test a novel compound, or combination of compounds, to concomitantly reverse adrenal insufficiency and muscle weakness in prolonged critical illness, while avoiding deleterious side-effects and aiming for synergy. Reaching this ambitious goal would represent ground-breaking progress.

ID: 210056

Start date: 01-10-2024

End date: 30-09-2029

Last modified: 11-10-2024

Concomitant Reversal of adrenal insufficiency and muscle weakness to enhance recovery from prolonged critical illness

GDPR Record

GDPR record

Have you registered personal data processing activities for this project?

- Not applicable

This project included personal data processing activities. Compliance with the General Data Protection Regulation for these activities is covered by the institutional Ethics Committee Research of the UZ/KU Leuven.

Concomitant Reversal of adrenal insufficiency and muscle weakness to enhance recovery from prolonged critical illness
DPIA

DPIA

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

- Not applicable

Concomitant Reversal of adrenal insufficiency and muscle weakness to enhance recovery from prolonged critical illness
ERC DMP +

Project information

Project Acronym

AdrenalWeakness

Project Number

101133276

Data summary

Summary

Objective 1		
WP1	Animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, xls files, tiff and jpeg files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (.doc, .ppt, .xls, .jmp, .sas files); <10 GB
	Human experiments	Existing data: "Postmortem-adrenals" - data from an observational study on postmortem tissue collection - study registry: doi.org/10.1186/ISRCTN49306926. Available and registered data include demographic data and relevant medical history. "DAS study" - data from an observational study on the time course of alterations in adrenal function - study registry: doi.org/10.1186/ISRCTN98806770. Available and registered data include demographic data and relevant medical history, information generated from patient monitors and therapeutic devices general laboratory analyses, drug prescription and delivery in ICU, laboratory analyses. "CROSS study" - data from an observational study on the time course of endocrine alterations and its consequences in critical illness - study registry: doi.org/10.1186/ISRCTN17621057. Available and registered data include demographic data and relevant medical history, information generated from patient monitors and therapeutic devices general laboratory analyses, drug prescription and delivery in ICU, laboratory analyses and muscle strength measurements. For each of the human clinical studies an existing study database in FilemakerPro is available. Novel human data will be collected and electronically stored in an encoded case record form, unambiguously linked to the source file. Raw data to be generated from these 3 datasets: tissue samples, blood samples, microscopy samples, information from laboratory measurements on available blood samples and tissue biopsies, RNA sequencing data - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB

WP2	Animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: xls files, tiff and jpeg files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
Objective 2		
WP3	Animal experiments	Available data: information from mice experiments, blood and tissues from experiments in WP1 Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters ((pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
	Human experiments	Existing data: "Postmortem-adrenals" - data from an observational study on postmortem tissue collection - study registry: doi.org/10.1186/ISRCTN49306926. Available and registered data include demographic data and relevant medical history. "CROSS study" - data from an observational study on the time course of endocrine alterations and its consequences in critical illness - study registry: doi.org/10.1186/ISRCTN17621057. Available and registered data include demographic data and relevant medical history, information generated from patient monitors and therapeutic devices general laboratory analyses, drug prescription and delivery in ICU, laboratory analyses and muscle strength measurements. For each of the human clinical studies an existing study database in FilemakerPro is available. Novel human data will be collected and electronically stored in an encoded case record form, unambiguously linked to the source file. Raw data to be generated from these 2 datasets: tissue samples, blood samples, microscopy samples, information from laboratory measurements on available blood samples and tissue biopsies, RNA sequencing data - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
WP4	animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
Objective 3		
WP5	animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB

	human experiments	Existing data: "PEPaNIC trial" - data from a mulitcenter randomized controlled trial that investigated the impact of omitting early forceful feeding in pediatric ICU patients - study registry: https://clinicaltrials.gov/study/NCT01536275. Available and registered data include demographic data and relevant medical history, information generated from patient monitors and therapeutic devices general laboratory analyses, drug prescription and delivery in ICU, laboratory analyses and muscle strength measurements. "TGC-Fast trial" - data from a mulitcenter randomized controlled trial that investigated the impact of liberal versus tight blood glucose control in the context of fasting in ICU patients - study registry: https://clinicaltrials.gov/study/NCT03665207. Available and registered data include demographic data and relevant medical history, information generated from patient monitors and therapeutic devices general laboratory analyses, drug prescription and delivery in ICU, laboratory analyses and muscle strength measurements. For each of the human clinical studies an existing study database in FilemakerPro is available. Novel human data will be collected and electronically stored in an encoded case record form, unambiguously linked to the source file. Raw data to be generated from these 2 datasets: tissue samples, blood samples, microscopy samples, information from laboratory measurements on available blood samples and tissue biopsies, RNA sequencing data - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
WP6	animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
Objective 4		
WP7	animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
WP8	animal experiments	Raw data to be generated: information from mice experiments, blood and tissues, and experimental laboratory measurements - format: tissue samples, blood samples, microscopy samples, fastq, pdf, png, tiff, jpeg, svg, doc, xls files, lab equipment specific software files, accompanying notes in paper lab notebooks, all documented following good laboratory practices and established lab procedures volume <100 GB. Processed data: bioinformatics and statistical analysis of the existing data, presentations, reports, manuscripts and posters (pdf, png, tiff, jpeg, svg, doc, ppt, xls, jmp, sas, R, RMD files); <10 GB
Objective 5		
WP9	human experiments	These trials need further planning based on the data that will become available in the previous WP's. The data management plan with the required information on data collection and processing operations will be part of the protocols that will have to be approved by the Institutional Ethical Review Board for this phase 1 and phase 2 trial. Further details will be added to this data management plan in due time.
WP10	trial design (no experimentation)	Raw data to be generated: pdf, png, tiff, jpeg, svg, doc, xls files Processed data: presentations and reports (pdf, png, tiff, jpeg, svg, doc, ppt files); <10 GB

FAIR data

1. Making data findable

All data are stored in structured Filemaker databases. All characteristics can be queried to retrieve specific participants or samples. Data can be exported as Excel files or csv files. The full study protocols describe data collection and definition of variables. Standing operating procedures are in place to describe data collection. For individual data elements requiring explanation, a definition is provided as info label in the structured database. All these documents are stored electronically in the structured study master file. We will keep a separate registry documenting the names and locations for raw and processed data exports as used for every step in the project.

As soon as robust and conclusive data analyses will be achieved, data will be deposited in the Research Data Repository (RDR) of KU Leuven (https://rdr.kuleuven.be/) and will be available to the community upon reasonable request.

2. Making data openly accessible

As soon as robust and conclusive data analyses will be achieved, data will be deposited in the Research Data Repository (RDR) of KU Leuven (https://rdr.kuleuven.be/) and will be available to the community upon reasonable request.

All materials/resources reused or newly generated in the project will be stored in-house and will be freely available to the community upon reasonable request.

The clinical databases contain sensitive and personal information. Although the data are pseudonymized, theoretically, it could be possible to identify a patient based on a combination of demographic characteristics and admission date/diagnosis. Therefore, it is important to only share those data that are necessary to answer a specific research question. Study questions that fall outside the original study question are subject to ethical approval. Hence, as data sharing would occur in the context of a new study question, ethical approval would be needed.

3. Making data interoperable

Data will be deposited in a format that can be accessible for everyone, and that is widely used as a standard in our scientific discipline. Mostly csv, txt and pdf file formats will be released to the KULeuven RDR.

4. Increase data re-use

Information on the research outputs and how to reuse/process released data with specific programs, software, workflows, etc. (including version number and parameters initially used) will be clearly described in the different depositories, where data will be accessible via the identifiers described above upon request.

The clinical databases contain sensitive and personal information. Although the data are pseudonymized, theoretically, it could be possible to identify a patient based on a combination of demographic characteristics and admission date/diagnosis. Therefore, it is important to only share those data that are necessary to answer a specific research question. Study questions that fall outside the original study question are subject to ethical approval. Hence, as data sharing would occur in the context of a new study question, ethical approval would be needed.

5. Allocation of resources and data security

According to our plans, there will be no cost to make data and research outputs FAIR in this project, as repositories and other resources are provided by free, open access platforms. Data preservation on UZ Leuven servers is currently free of costs. Data preservation on KULeuven servers will be paid by other budgets of the laboratory of intensive care medicine.

All study databases are protected, accessible only with restricted user ID and password. Access control is set at network, directory and database level. User access and changes in the databases are recorded.