Plan Overview

A Data Management Plan created using DMPonline

Title: Hepatit virus patogenes och strategier för att undvika immunförsvaret: Nya transgena musmodeller och nya behandlingsformer

Creator: Matti Sällberg

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Affiliation: Karolinska Institutet

Funder: Swedish Research Council

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Project abstract:

We have for almost three decades studied chronic infections caused by the hepatitis B virus (HBV), hepatitis C virus (HCV) and hepatitis D virus (HDV) as these cause severe liver disease and hepatocellular carcinoma (HCC). The past five years have significantly changed the possibility to treat some of these conditions and immunotherapies for HCC are being developed and tested. We here aim at understanding the pathobiology of these infections and to develop new treatment regimens. HCV used to be the major cause for liver transplantation in the Western world, but today >90% of those with chronic HCV can be cured using the new directly acting antivirals (DAAs; [1]). Still, to control and eradicate HCV a vaccine is needed, and those who remain uncured need alternative therapies. For HBV, HDV, and HCC caused by these infections there is a great need for “curative” therapies. Thus, we will use our extensive experience in basic and clinical research to develop new preventive and therapeutic immune therapies. The approach differs for the different diseases. For HCV, we have developed a unique mouse model [2]. In this model we can in detail understand T cell dysfunction induced by HCV replication. We are trough different technologies trying to understand the mechanism behind the immune modulatory effect of the HCV replication itself. This is essential when we explore new concepts for preventive immunotherapies using DNA, RNA and viral vectors through international collaborations. For HBV our major goal is to develop an immunotherapy induce off-therapy control of HBV. When the HBV replication is controlled this reduces the risk of liver disease as well as a reduced infectivity. We have done significant progress in the past year, with a potent immunotherapy candidate ready for clinical testing, and a completely new chimeric antigen receptor (CAR; [3]) technology targeting the liver. HDV is an aggressive satellite virus to HBV for which there are no good therapies. We are generating both T cell therapies and an active immunotherapy. In conclusion, we are building on our previous experience to rapidly develop new immune therapies for these leading causes for liver disease.

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Copyright information:

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General Information

Project Title

Hepatit virus patogenes och strategier för att undvika immunförsvaret: Nya transgena musmodeller och nya behandlingsformer

Project Leader

Matti Sällberg

Registration number at the Swedish Research Council

2019-01681

Version

1

Date

200303

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Data is generated mainly during animal experimentation and analysis of human tissues. Eventually data will be generated in clinical trials.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

Data from in vitro experiments are generated through analysis of cells by RNA, DNA and protein analysis. These are stored in KIs ELN. Original pictures are scanned or generated electronically and saved as jpg files.

Data from animal experiments are generated through either analysis of living animals through inspection, weighing, and in vivo imagingsaved as jpg files. These are recorded in the journals of the animal faciliti and also introduced into ELN.

Analysis of immune responses are analyzed and data is stored in xls files. These data are then transferred to programs for analysis. This can be as xls or pzf files.

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

Stored in ELN and on paper and then transferred to ELN.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

All data is stored and all experiments are repeated with all original data points recorded

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

ELN is bascked up by KI servers. Data is also stored on multiple personal computers, which are backed up through the KI network and OneDrive.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

ELN requiers passwoer access. All paper files are stored in locked offices.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

All data is according to GDPR. We will not have any data that can identify a person. Any human data is pseudonymised and the key is stored in a locked cabinet with the responsible physician.

How is correct data handling according to ethical aspects safeguarded?

All experiments and data handling weill be according to ethical approvals.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

Data will be made accessible through publication and in supplemental material. Anyone who ask for data will obtain it. Some data will be accessible thrpugh public web sites for example opencorona/ki.se.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Using the KI ELN and back up systems.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

No. All data is accessible through commecial programmes.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

Through PUBMED and other public sources

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while

the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

The PI is responsible. after the retirement of the pi it will be ki servers and the ki internal documentation and archive system.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

These costs are covered by the KI INDI. Storage on ELN and publication ensures fulfillment of FAIR principles. Also, only commercial programmes are used to generate and interpret data in line with FAIR principles.