Plan Overview

A Data Management Plan created using DMPonline

Title: Predicting and preventing death from uveal melanoma

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Principal Investigator: Gustav Stålhammar

Data Manager: Gustav Stålhammar

Affiliation: Karolinska Institutet

Funder: Swedish Research Council

Template: Swedish Research Council Template

Project abstract:

In the planned research project, we aim to develop novel diagnostic and prognostic methods for uveal melanoma and test the clinical utility of adjuvant Melatonin to prevent the development of metastases. The overall purpose is to improve survival in this aggressive cancer. Why is this research important? • Uveal melanoma is the most common type of eye cancer in adults. • Nearly half of all patients eventually develop metastases and die from their disease. • Unlike virtually all other cancers, survival has not improved since the 1970s. Why should the research be carried out by the applicant? • The applicant is both an ophthalmologist and pathologist. His clinical and research activity is based at St. Erik Eye Hospital, with national health care responsibility for all Swedish patients with eye tumors, including uveal melanoma. • In addition to the access to patients, St Erik Eye Hospital has a comprehensive archive of eyes with a complete collection of the country's enucleated eyes with uveal melanoma since the 1960s. This is critical for this research. • The applicant has international research experience and a wide network of fellow researchers. What does research mean for our patients? • More accurate tests give each patient better information about their prognosis. • Blood tests may replace tissue samples from the tumor and reduce pain and risk of complications. • Additional treatment for patients at high risk of metastasis may reduce the mortality of the disease.

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Predicting and preventing death from uveal melanoma

General Information

Project Title

Predicting and preventing death from uveal melanoma

Project Leader

Gustav Stålhammar, Associate professor, M.D. Ph.D. FEBO

Registration number at the Swedish Research Council

Question not answered.

Version

3

Date

2020-09-17

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

How will data be collected, created or reused?

Data will be collected from patient journals and through our experiments on tumor tissues and peripheral blood samples. Further, data on patient survival will be collected.

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

Data on patient age, sex and survival will be collected. Further, we will collect tumor characteristics including size, shape and location. We will also collect data on concentrations of tumor related proteins in peripheral blood samples.
Our raw data volume will be in the range of 1-10 Gb
Our output data (for reports) will be in the range of 10-100 Mb

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.?

All data is coded by individual patient without unnecessary identifiable information and all data is gathered into an excel database.

This ensures good control. The Database is located at Karolinska Institutets ELN (Electronic Lab Notebook) in accordance with Karolinska Institutets guidelines for Research Data Management.

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

Data from tumor tissues and blood samples are to be saved as soon as possible after collection or generation. As our research consists of several smaller experiments rather than continous or longitudinal experiments, we will create one database for every experiment and not one database that is continously updated. The database includes experimental, tumor and patient data. We will also collect data from patient medical records, including data on survival.

Storage and backup

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

The Karolinska Institutet ELN (Electronic Lab Notebook) is continuously backed up.

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

The database is fully password protected for local access only.

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?

In accordance with GDPR we have minimized the amount of data collected to the bare minimum needed for analyses. The info is fully traceable because there is a locked key to decode study IDs to personal numbers. Only the project management have access to this.

How is correct data handling according to ethical aspects safeguarded?

Safe data storage system, with full traceability in accordance with Ethical permissions.

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?

The data is accessed for analyses purposes only by Stålhammar and Girnita lab members and clinical study coordinators. A minimal number of individuals have access as imposed by GDPR. Longterm storage is ensured by backup of the relative database within the KI firewall.

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

Yes by Stålhammar lab data manager responsible for data infrastructure.

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?

The database will not be made available for anyone outside the project, neither in near-term or long-term. However, selected parts of the database, without tracable or sensitive patient information may be shared in conjunction with publications. This is to ensure transparency and reproducibility.

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

These are only available to study coordinators within our closed database.

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?

St. Erik Eye Hospital Data protection officer is Oskar Nordahl. All management of data is directed by Gustav Stålhammar his lab members involved in the study.

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?

Dedicated computers are in place. All necessary infrastructure is available and suitable to esure FAIR principles.