Copy of Predicting and preventing death from uveal melanoma

A Data Management Plan created using DMPonline

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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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General Information

Predicting and preventing death from uveal melanoma

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Question not answered.

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

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.

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

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.

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

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

The database is fully password protected for local access only.

Legal and ethical aspects

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.

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

Accessibility and long-term storage

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.

Yes by Stålhammar lab data manager responsible for data infrastructure.

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.

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

Responsibility and resources

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.

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