
Characterisation of the Tumour Microenvironment in Vestibular Schwannoma

A Data Management Plan created using DMPonline

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Project abstract:

Vestibular schwannoma (VS) are benign tumours arising from the vestibular component of the VIII cranial nerve. Whilst 95% occur as a unilateral, sporadic entity, they can also occur bilaterally as part of the dominantly inherited tumour syndrome, neurofibromatosis type 2. Although histologically benign tumours the associated morbidity of both the tumour and the treatment thereof can be considerable. The management of sporadic VS can be problematic due to their variable size at presentation and their unpredictable and sometimes rapid growth whereas involvement of both VIII cranial nerves by NF2 related VS makes management of these lesions especially challenging. The pathophysiological mechanisms that trigger and maintain growth in VS are incompletely understood. Whilst considerable progress has been made in deciphering the role of Merlin and the downstream molecular pathways in VS pathogenesis other aspects of the tumour microenvironment, in particular the role of inflammation, have not been extensively studied. Preliminary data published by our group and others suggest that within VS inflammation plays a key role in driving tumour growth and a hypothesis can be formed that within growing tumours, production of pro-inflammatory mediators by neoplastic Schwann cells promotes migration of inflammatory cells from the vasculature into the tumour. This research aims to characterise the exact nature of this process, with the aim of ultimately identifying targetable pathways to attenuate the growth of these tumours.

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Manchester Data Management Outline

- Ethics
- Funder

- No - only institution involved

- Re-use existing data (please list below)
- Acquire new data

Within a cohort of patients that have been identified via an existing clinical database, clinical data which has been gathered as part of these patients' care will be accessed and utilised as part of this research project. This data will include information regarding the patients' medical history, clinical assessment at the time of presentation and the results of imaging studies.

- Other storage system (please list below)

Consent forms will be stored in a locked filing cabinet in an office accessible by keypad in the Clinical Sciences Building at Salford Royal NHS Foundation Trust. Consent forms will be destroyed when all of the relevant research data is anonymised, this will take place when the relevant aspects of the medical records have been accessed and the data collected.

The data collected will be stored in password protected Excel spreadsheets on the SRFT NHS server. All files will be password protected, and only members of the direct care team will have access to files containing patient identifiable information. Members of the research team will have access to anonymised data. The passwords for the data will not be shared to anyone outside of the research team. Data generated from research within the study team will be stored on NHS computers for a maximum of 20 years from date of last publication.

- < 1 TB

- No

- 11 - 20 years

- Pseudonymised personal data
- Anonymised personal data
- Special categories and criminal convictions
- Personal information, including signed consent forms

With respect to the prospective cohort of patients, these patients have/will have provided written, informed consent allowing access to their medical records and to access excess tumour tissue not required for clinical diagnostic work (via a separate ethically approved biobank, The Manchester Brain Tumour BioBank). The consent forms will be signed and dated by the patients, and stored until the data provided by accessing their medical records has been anonymised. These consent forms will be stored securely as described above.

We are in the process of applying for ethical approval to access the medical records and excess tumour tissue of a cohort of patients that did not provide consent at the time of their surgery, in accordance with the Medical Research Council guidance on the use of existing clinical archives.

All patient data will be pseudo-anonymised with the use of their hospital number as the identifier. No other patient identifiable information will be collected as part of this study. The data will be stored in password encrypted Microsoft Excel spreadsheets stored on the Salford Royal Foundation Trust server. The password will be known only to members of the research team, and the server is only accessible to members of Salford Royal Foundation Trust.

- Yes – the project relies on identifiable personal data in order to be understood

- Yes - Public institutions with contractual arrangements (e.g. NHS research sites)

- No

- Yes

Prof. Andrew King

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Project details

The primary objective of the proposed study is to build upon our previous study findings and establish, through a large immunohistochemistry (IHC) analysis of previously resected tumour tissue, whether inflammation is a consistent feature within NF2 related and sporadic VS. Through this study we hope to not only establish the relationship between inflammation and tumour behaviour (size, growth rate) but also the key mediators (cytokines, chemokines) driving this inflammation with a view to identifying novel immune-related therapeutic targets.

A second question, having established the role that inflammation plays in tumour growth, is how can we quantify the inflammatory burden within an individual tumour and thereby stratify patients who may benefit most from immune targeting therapy. A blood-based biomarker which allows assessment of intratumoural inflammation but also helps identify the key systemic mediators driving this process would therefore be desirable. A second objective of the proposed study is to therefore establish through a prospective pilot study if plasma cytokine expression levels can be used as a biomarker of both tumour growth and intratumoural inflammation within sporadic VS.

University of Manchester Data Management Policy
Northern Care Alliance Privacy Policy

Responsibilities and Resources

Mr. Cathal Hannan-Data Collection, Data Management, Data Analysis
Prof. Andrew King-Project Supervision

None in addition to those already provided as a member of staff at SRFT

Data Collection

Patient Details-As described above, all data will be pseudo-anonymised by the use of a unique study number as the patient identifier. Data will be collected on the patients' medical history, their clinical assessment on presentation and the results of imaging studies. These will be collected in conjunction with information derived from the analysis of the patients' tumour tissue and peripheral blood. This data will be stored in password encrypted Microsoft Excel spreadsheets on the Salford Royal Foundation Trust NHS server. Access to the data will be restricted to a small number of people (<10) involved in this research project. We do not anticipate that this data will be re-used outside this research project.

All data will be collected by a single researcher (Mr. Cathal Hannan). All data will be collected using a standardised template within the aforementioned Microsoft Excel spreadsheets.

Documentation and Metadata

The file names of the data will include descriptive titles, detailing exactly which group of patients are represented in the data stored therein. The date the databases were created will form part of the file information stored on the computers. The data will be created by review of the patients' electronic patient record, as well as by review of their tumour tissue and peripheral blood. This will be evident to secondary users on review of the database. All information will be stored within password encrypted Microsoft Excel spreadsheets.

Ethics and Legal Compliance

As previously mentioned, the data will be pseudo-anonymised via the use of a unique study number as the patient identifier. Ethical approval is currently being sought from the University of Manchester research ethics committee. All patients within the prospective cohort of this study will be asked to provide written consent for their tissue to be stored in the Manchester Brain Tumour BioBank and accessed for the purposes of research. With respect to access to the tumour tissue and medical records of the retrospective cohort of patients, we are in the process of obtaining ethical approval for this from an NHS REC and the HRA.

The copyright and IPR will be owned by Mr. Cathal Hannan, as a student at the University of Manchester and in line with university policy in this regard. No patentable data will be included in the research databases.

Storage and backup

The data will not be stored on laptops or external storage devices. At all times the data will be stored on the SRFT NHS server, which is backed up daily. As mentioned above, the data will be stored in password encrypted Microsoft Excel spreadsheets.

Data access will be regulated by the use of password protected files. These files will be stored on the SRFT NHS server, which is backed up daily. The SRFT NHS server is only accessible to employees of the trust. The password will be known to a small number of people (<10) who are directly involved in the research. The data will be directly collected using SRFT PCs, obviating the need for transfer of information from less secure forms of storage.

Selection and Preservation

The data gathered may be useful in the future to correlate clinical data (particularly with respect to tumour growth history) with pathological/peripheral blood markers of interest that have yet to be identified. Following the completion of this PhD project (August 2022) the data with respect to radiological evidence of tumour growth will be kept for a further 20 years in the pre-existing research databases.

The data collected will be destroyed 20 years following the final publication as a result of this research.

Data Sharing

Fully anonymised data will be shared with researchers at the University of Manchester using Dropbox for Business. We do not anticipate the need to share data that is not anonymised.

Yes. Data containing patient identifiable information can not be shared with anyone outside of the direct care team. For this reason, only fully anonymised data will be shared with other researchers.