Plan Overview

A Data Management Plan created using DMPonline

Title: Comparison of oncological and surgical outcomes between formal pancreatic resections and parenchyma-sparing resections for small PanNETs (< 2 cm)

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Comparison of oncological and surgical outcomes between formal pancreatic resections and parenchyma-sparing resections for small PanNETs (< 2 cm)

Data Collection

What data will you collect or create?

- Clinical and pathological predictors for lymph node metastases of tumors treated by formal oncological resection will be analyzed. Demographic characteristics, clinical presentation, radiological variables including location, size, bile duct and main pancreatic duct dilatation, intraparenchymal or exophytic radiological pattern, preoperative Ki67 labeling index, somatostatin receptor imaging data will be included in the study.

How will the data be collected or created?

The hospitals which are European Neuroendocrine Tumours Centres of excellence will have a prospectively collected database of patients with pancreatic neuroendocrine tumours. This should also have tumour size recorded and will help with the identification of the patients for the study.

The majority of the data may have already been collected as part of this. However, if the parameters are missing then the person collecting the data may need to either look up patient's pathological reports or imaging reports on the medical notes (either in paper form or electronic patient's records).

The data should curated on the excel spreadsheet which has been specifically designed for this study. There are clearly titled headings per column with comments added explaining what kind of data it should contain. There is also another sheet on the spreadsheet with definitions of terms. If the person collecting the data has any questions they can email any of the pancreatic 2000 team members.

We ask all the centres taking part to register the study with their local research and development department. The data should only be kept in their hospital computers. We ask when the data is ready for transfer to the primary investigators of the project, to be anonymised by allocating study number to these patients (no and initial of the institution) so that the team members who are analysing the data will not have no patient identifiable information.

Documentation and Metadata

What documentation and metadata will accompany the data?

We ask the people who are collecting the data to also fill in a form with their own normal ranges for their biochemical tests. Otherwise, the other data (such as scans, pathological terms) are all standardised information across the institution.

Ethics and Legal Compliance

How will you manage any ethical issues?

We advise each institution involved in the study to register the study and obtain ethical approval if required as different institutions and countries will have their own approval systems.

In the NHS, use of data or creation of database does not require ethical approval.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The University of Southampton will hold copyright in the primary data generated by the research throughout the project. The University will also hold the copyright in any database created to collate already pubished data, however if necessary, consent will be sought and acknowledgement will be provided to third parties who may retain rights over some of the data used

Storage and Backup

How will the data be stored and backed up during the research?

All data generated will immediately be transferred and stored in the University of Southampton iSolutions secure research data storage service. The data stored within this facility is regularly backed up and a copy of the back-up, regularly off-sited to a secure location for disaster recovery purposes. Only authorised users can access data stored within this facility and it is managed under the governance of the University of Southampton Research Data Management Policy (http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html).

How will you manage access and security?

All data generated will immediately be transferred and stored in the University of Southampton iSolutions secure research data storage service. The data stored within this facility is regularly backed up and a copy of the back-up, regularly off-sited to a secure location for disaster recovery purposes. Only authorised users can access data stored within this facility and it is managed under the governance of the University of Southampton Research Data Management Policy (http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html).

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Metadata records for the data (and published outputs) will also be maintained on the University of Southampton Institutional Research Repository. In accordance with the University's Data policy, the data will be archived from a minimum of ten years after publication or last access, whichever is longer (seehttp://www.calendar.soton.ac.uk/sectionIV/research-data-management.html). DOIs will be issued for the dataset and data subsets as per the University's DOI policy (seehttp://library.soton.ac.uk/identifiers/doipolicy).

Future users of the data will be bound by data sharing agreements. Where suitable a licence (currently Creative Commons) can be applied to data deposited in the repository.

What is the long-term preservation plan for the dataset?

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Data Sharing

How will you share the data?

The result of the study will be published in a peer-reviewed journal. If any researcher from the institution who participated in the study would like access to data, then we encourage them to contact the corresponding author. However, in any future published work were to be made based on the data collected for this study, all the participating centres and people involved should be listed in the collaborators list of the publication.

Are any restrictions on data sharing required?

After the study is completed, the data, metadata and the code used will be stored for 10 years. If any researchers would like access to the data, please contact the primary investigator or the corresponding authors of any published work from this project.

Responsibilities and Resources

Who will be responsible for data management?

The primary investigator and the member of the pancreas2000 project group for NET2000 will be responsible for data management.

What resources will you require to deliver your plan?

Anyone who is taking part in the study will have access to this data management plan, study protocol and data collection sheets.