Manchester Cartilage Retrieval Centre

A Data Management Plan created using DMPonline

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Project abstract:

This project will collect tissue from any failed cartilage surgery. The Manchester Cartilage Retrieval Centre will offer the service to all orthopaedic surgeons in the UK who are undertaking cartilage repair surgery. Tissues from failed cartilage surgery will be sent to the University of Manchester and then analysed histologically, with the aim to identify a mechanism of failure. There is currently no such service offered in the UK, meaning that surgeons have no way of determining why some approaches are failing in their patients. The analyses carried out on these tissues may help identify why some approaches are unsuccessful and could be used to inform future research into improving the success of cartilage repair surgery. It may also be possible to identify factors that contribute to an unsuccessful surgery, leading to guidelines about what sorts of approaches are best used with which kinds of patients.

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Manchester Cartilage Retrieval Centre

Manchester Data Management Outline

- Yes

This project has enough money to start using the PIs existing consumables money. We will begin seeking further financial support in the near future.

- Yes - only institution involved
- Acquire new data
- University of Manchester Research Data Storage Service (Isilon)
- 1 - 8 TB
- Not applicable
- 5 - 10 years

The hard copies of non-patient identifiable data will be kept in secure locked storage in a research office at at the University of Manchester for 10 years. The electronic data will be stored as a non-patient identifiable database on encrypted University of Manchester computers for 10 years.
Anonymous samples of tissue donated to the University of Manchester will also kept for 10 years at the University of Manchester. The principle investigator, sponsor representative and study monitors will have access to the data if required.
It will be carefully explained to patients that their samples will be retained for up to 10 years (as opposed to the usual 5) to complete the analyses on their tissue and to answer research questions that arise from the analyses.

- Anonymised personal data
- Personal information

Patient Information:
Orthopaedic surgeons who submit tissue samples to this service will be asked to fill in a Patient Data sheet with the following anonymous details about the patient:
Sex, age, clinical diagnosis and mechanism of injury (if known), date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the revision surgery approach.
The orthopaedic surgeons will be asked to label the samples and the Patient Data sheet as follows: Surname of Surgeon_Hospital_Date - Thus no identifiable information about the patient will be communicated to the research team at The University of Manchester.
If more than one donation is sent to the service on the same day from the same surgeon, the labels should be formatted as follows: Surname of Surgeon_Hospital_Date_1, Surname of Surgeon_Hospital_Date_2 etc.
Surgeon Information:
A report on each tissue sample will be created by researchers and clinicians involved in the service once all laboratory assessments have been completed. This anonymous report will be sent to the consultant surgeon from an NHS email account to an NHS or Spire Healthcare email account. The surgeon will be able to identify the patient by looking through their surgical lists and comparing this information to the clinical information and date of surgery detailed in the report. The surgeon will be responsible for communicating the information in the report to the patient.
For this system to work, the research team will need to collect the following information about the consultant surgeon:
Name, hospital, NHS/Spire Healthcare email address.

Patient information:
Only anonymous patient data will be collected: Sex, age, clinical diagnosis and mechanism of injury (if known), date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the revision surgery approach.
This information will be provided by the orthopaedic surgeon in a paper document (Patient Data sheet) which will be sent to the University of Manchester with the donated tissue sample(s). These Patient Data sheets will be kept in locked cabinets in a locked research office at The University of Manchester. Only members of the research team will have access to the room and cabinet.
The information detailed in the Patient Data sheet will be digitised by a member of the research team. This will be in Microsoft Excel format and will be saved in a folder in a digital trial master file, which will be organised as per current GCP guidelines. Filenames will also follow current GCP guidelines, and the document will be checked by a second member of the research team to reduce the risk of data entry errors. The Excel document will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.
Samples of tissue removed during the revision treatment will be labelled by the clinician using the format 'Surgeon_Hospital_Date'. Thus, researchers at the University will be able to match the anonymised information in the Patient Data Sheet to the sample itself using this ID. The researchers will be unable to determine the identity of the individual who dontated the sample from the information available to them.
Surgeon information:
The following personally identifiable information will be retained: Name, hospital, NHS/Spire Healthcare email address.
This information will be provided by the orthopaedic surgeon in a paper document (Patient Data sheet) which will be sent to the University of

Manchester with the donated tissue sample(s). These Patient Data sheets will be kept in locked cabinets in a locked research office at The University of Manchester. Only members of the research team will have access to the room and cabinet.

The information detailed in the Patient Data sheet will be digitised by a member of the research team. This will be in Microsoft Excel format and will be saved in a folder in a digital trial master file, which will be organised as per current GCP guidelines. Filenames will also follow current GCP guidelines, and the document will be checked by a second member of the research team to reduce the risk of data entry errors. The Excel document will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.

- No

We will not be storing any personal information of patients, but the personal information of surgeons will be retained for 10 years.

- No
- Not applicable
- Yes

The data collected from patients (e.g. age, sex, clinical diagnosis etc.) from which the samples came may be used in future research, but this data will all be anonymous. No personal identifiable information will be collected nor used for future purposes.

The personal information collected from surgeons will not be used for future purposes.

Leela Biant

10/04/2019

Project details

This service will collect and analyse samples of tissue from failed cartilage repair surgery with the aim to determine mechanism of failure. This information could aid clinicians in future to identify which surgical approaches in cartilage repair are most successful.

The General Data Protection Regulation (GDPR) will be adhered to, as will policies of the research group, department, and institution including The University of Manchester Records Management Policy, The University of Manchester Data Protection Policy, The University of Manchester Research Data Management Policy and the University of Manchester IT Policies and Guidelines. The University guidelines which will be adhered to are as follow:

The University of Manchester Research Data Management Policy
http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=33802%20
The University of Manchester Records Management Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14916
The University of Manchester Data Protection Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14914
The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=28526
The University of Manchester Intellectual Property Policy
http://documents.manchester.ac.uk/display.aspx?DocID=24420
The University of Manchester IT policies and guidelines
http://www.itservices.manchester.ac.uk/aboutus/policy/

The Human Tissue Act will also apply to this study as it will involve the storage and analysis of human tissue. Guidelines on management, storage and security of the cells used in this study published by the Human Tissue Authority will be adhered to.

Responsibilities and Resources

The Principle Investigator, Professor Leela Biant will be responsible for data management. She will delegate day to day data management tasks to members of the research team.

Ultimately, all members of the research team will be responsible for digitising and securely storing the anonymous hard and digital copies of Patient Data sheets (sex, age, diagnosis etc.). They will also be responsible for quality control and organisation of the data collected.

The research team at The University of Manchester will also be responsible for collecting and securely storing the tissue samples. They will also be responsible for collecting data from the anonymous tissue samples obtained in the laboratory, as well as securely storing this data, checking its quality and organising it in an appropriate manner.

Access to a lockable filing cabinet and room for storage of the hard copies at the University of Manchester, and access to the University of Manchester Research Data Storage service will be required to deliver this plan. There will be no storage costs associated with this part of the study, nor will research staff be required to undergo any relevant training for this investigation.

The samples of tissue provided by patients will be stored securely in laboratories at the University of Manchester.

Data Collection

Patient Data Form:

1. Anonymous patient information: Sex, age, clinical diagnosis and mechanism of injury (if known), date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the revision surgery approach. A sample ID will also be written on the form in the format of 'Surgeon_Hospital_Date'.

2. Surgeon information: Name, hospital, NHS or Spire Healthcare email address

The original copy will be on paper and will be filled out by the surgeon after the tissue sample is removed. This sheet will then be sent to The University of Manchester with the sample. The Patient Data form will then be digitised by researchers at The University of Manchester.

Tissue Sample: Sample ID written in the form of 'Surgeon_Hospital_Date'. The clinician removing the sample will write this information onto a sticker which will be placed onto the container containing the sample so that the researchers at the university can match the donation to the Patient Data sheet.

Histological analyses will be carried out on the samples at The University of Manchester.

Orthopaedic surgeons will identify patients who are undergoing a revision procedure for a cartilage repair surgery from their surgical lists.

Prior to the procedure, the surgeon will be responsible for discussing the option to donate the tissue to The University of Manchester. If the patient verbally consents, the tissue which would routinely be removed and destroyed will instead be retained and sent to The University of Manchester for analysis. The surgeon will label the sample and fill in a Patient Data form to go along with the sample then arrange with the Manchester Cartilage Retrieval Centre for the sample to be collected and transported to the University of Manchester.

On arrival, a member of the research team will securely store the sample then digitise the Patient Data form. The hard copy will then be stored with the master file in a locked filing cabinet in a locked research office. The data entry will be validated by another clinical member of the research team at a later date to minimise human error in transcribing the paper data to the electronic spreadsheet.

The electronic copies of the data will be stored in an electronic master file which will be organised as per current Good Clinical Practice (GCP) Guidelines. File names will also follow reccomendations by GCP (including filename conventions). The data collected from each individual will be stored in an excel file.

A hard copy of the study master file will also be created and stored under lock and key with the Patient Data forms. This will be maintained by the research team, and will also be organised as per current GCP guidelines and recommendation.

Histological analyses will be carried out on the samples at The University of Manchester. Repeated tests will be carried out on these samples to ensure reliability. All instruments will be calibrated as per the manufacturers guidelines before use, and standardised methods will be used to collect the data. The data will be peer reviewed.

Documentation and Metadata

An explanation of how researchers can access the data collected during this study will be given in the master file. This file will include all essential information on the study including the names of researchers involved, the aims and background of the study, the methods used (protocol) and information on how to interpret the data collected. Once the study is complete, an overview of the results will also be added to the study master file.

Ethics and Legal Compliance

No identifiable information about patients will be given to researchers at the University of Manchester. Each sample in this study will be given a unique ID to anonymise the data. Only the surgeons who send the sample and are directly involved in the patient's care will have access to identifiable data.

The name, hospital and NHS or Spire Healthcare email addresses of the surgeons who send samples will be stored for the purpose of this centre. This will enable the researchers to communicate the results of the analyses on the tissues to the surgeon from whom the sample was sent. The hard copies of Patient Data forms which will include the personal information of surgeons will be kept in a locked filing cabinet in a locked research office. Only researchers named on the project will have access to the office and filing cabinet. The digitised version of this document will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.

The study will be referred to a local NHS Research Ethics Committee for approval (via the Integrated Research Application System), as the samples will be coming from UK hospitals. The study will not commence until approval has been granted.

Verbal consent by the orthopaedic surgeon will be taken from each patient prior to their donation being sent to the University of Manchester. Participants will be free to withdraw from the study at any time by informing their surgeon verbally or in written form. The surgeon will be responsible for informing the research team of patients who wish to withdraw their sample. Participants will not be required to give a reason for withdrawing from the study. Their legal rights will not be affected by their withdrawal. Data already collected with consent would be retained and used in the study.

Consent from the surgeon to share their name, hospital and email address with the University of Manchester will be assumed by the fact that the surgeon will have completed the above information him/herself and organised for the sample to be analysed at the University of Manchester.

The study data will be kept for 10 years as a non-patient identifiable database on university servers. The master file and hard copies of data will be kept for 10 years in secure locked storage on site in a research office at the University of Manchester. The chief investigator, sponsor representative and study monitors will have access if required.

We intend to disseminate this work as personalised reports for surgeons, peer-reviewed scientific journals, conference presentations and by publications on websites. No patient or surgeon identifiable information will be published.

The University of Manchester own the copyright and IPR of any new and existing data.

Storage and backup

The hard copies of data will be stored in a locked filing cabinet in a locked room at the University of Manchester.

All electronic data will be stored on the University of Manchester Research Data Storage system which is backed up every day and is secure.

All human tissue will be stored in an appropriate laboratory in accordance with the guidelines and standards of the Human Tissue Authority

Only those listed in the protocol as study researchers will be given access to the data. The key for the hard copies of data will be kept in a location only known to the involved researchers.

Access to the anonymous electronic data will be restricted to the involved researchers. This restriction will be put in place by the IT team at the University of Manchester who are responsible for granting access to staff members using the University of Manchester
Research Data Storage system. The PI will inform the IT team who can access the data. All those with access will be required to enter a password to access the data.

The data will not be shared with anyone outside the University of Manchester.

Selection and Preservation

The study data will be kept for 10 years on a database on encrypted university computers. This data will include all anonymised results and the analysis and observations of these results. The anonymised data will be shared with the surgeon. Group analyses of anonymised data will be shared on Mendeley - the university recommended respository.

The master file and hard copies of data will be kept for 10 years in secure locked storage on hospital site. The chief investigator, sponsor representative and study monitors will have access if required.

The study data will be kept for 10 years on a database on encrypted university computers. This data will include all anonymised results and the analysis and observations of these results. The anonymised data will be shared with the surgeon. Group analyses of anonymised data will be shared on Mendeley - the university recommended respository.

The master file and hard copies of data will be kept for 10 years in secure locked storage on hospital site. The chief investigator, sponsor representative and study monitors will have access if required.

Data Sharing

The anonymous data from the analyses on each individual sample will be shared with the surgeon who ordered the analyses. Anonymised group data will be made publicly available via the university recommended repository (Mendeley) at the end of the project. The GDPR will be adhered to with respect to data sharing.

Research on multiple anonymous samples will be reported through peer reviewed academic journals. The findings will be made public through public engagement events. There is no public database for registering this form of research.

To comply with the Open Access Policy (2016), all published research will be made publicly accessible via green or gold access and a Data Access Statement will be made available with the publication. Journal restrictions will be adhered to.

Only anonymised data will be shared to the public.