Plan Overview

A Data Management Plan created using DMPonline

Title: Biomarkers of Shoulder Pathologies in Synovial Fluid

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Affiliation: University of Manchester

Template: University of Manchester Generic Template

Project abstract:

A biomarker is defined as ‘a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention’. There are many examples of the use of biomarkers in clinical practice, but few of value in the diagnosis and prognosis of shoulder pathologies such as frozen shoulder. Approximately 2-5% of individuals with shoulder pain are diagnosed with frozen shoulder. The symptoms of pain and limited function associated with frozen shoulder can fluctuate over the course of months or years. Due to the seeming unpredictability of the condition, clinicians can only broadly identify whether the joint is freezing, frozen or thawing – they cannot to predict how long the patient will display symptoms for. Improving our knowledge of biomarkers of frozen shoulder could provide new routes for better diagnosis, prognosis and treatment for this condition. Of the studies which have investigated biomarkers of shoulder pathologies, most have concentrated on imaging biomarkers identified from scans or inflammation biomarkers identified from blood samples; both approaches increase treatment costs for healthcare providers. This study will aim to identify biomarkers of frozen shoulder from samples of synovial fluid. Synovial fluid is a lubricating fluid present in joints. Samples of synovial fluid can be taken by clinicians during routine clinical or surgical treatments of frozen shoulder. Not only does this approach eliminate additional staffing and scanning costs, it saves time and ensures that patients are not required to undergo any procedures in addition to the standard of care. In order to be able to identify biomarkers of frozen shoulder, it will be necessary to also collect synovial fluid from age-matched patients with other shoulder pathologies which do not cause symptoms that are consistent with frozen shoulder. We are therefore proposing to collect synovial fluid of patients with shoulder pathologies during routine clinical and surgical treatments for the investigation of biomarkers in frozen shoulder. This study will use discovery proteomics to identify biomarkers of frozen shoulder.

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Biomarkers of Shoulder Pathologies in Synovial Fluid

Manchester Data Management Outline

1. Is this project already funded?

- Yes

Will you be applying for funding from any of the following sources? If your funder isn't listed, please enter in the free text box provided.

Project funded using £4,000 from PI's consumables account, which has now been transferred to Prof Tony Freemont's lab for the study.

3. Is The University of Manchester the lead institution for this project?

- Yes - only institution involved

4. What data will you use in this project (please select all that apply)?

- Acquire new data

5. Where will the data be stored and backed-up during the project lifetime?

- University of Manchester Research Data Storage Service (Isilon)
- Other storage system (please list below)

The hard copies of data (consent forms and patient data sheets) will be kept in secure locked storage in a research office at one of the involved NHS hospitals for 10 years (Trafford General Hospital, Wythenshaw Hospital, Manchester Royal Infirmary).

The electronic data will be stored as a non-patient identifiable databases (pseudo-anonymised) on encrypted University of Manchester computers for 10 years. The University of Manchester Research Data Storage Service will be used. Two discreet folders within the Service will be used. One folder will be created for depositing the pseudo-anonymised data collected in the clinic (sex, age, diagnosis) - the clinicians and researchers will have access to this folder. A second folder will be created for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

Pseudo-anonymous samples of synovial fluid will also kept for 10 years at the University of Manchester as per University of Manchester guidelines.

6. If you will be using Research Data Storage, how much storage will you require?

- 1 - 8 TB

7. If you have a contractual agreement with a 3rd party data provider will any of the data associated with this project be sourced from, processed or stored outside of the institutions and groups stated on your agreement?

- Not applicable

8. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

The hard copies of data will be kept in secure locked storage on site in a research office at one of the involved NHS hospitals for 10 years (Trafford General Hospital, Wythenshaw Hospital, Manchester Royal Infirmary).

The electronic data will be stored as a non-patient identifiable databases on encrypted University of Manchester computers for 10 years.

Pseudo-anonymous samples of synovial fluid 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 current research and to answer research questions that arise from it.

Questions about personal information

Personal information or personal data, the two terms are often used interchangeably, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

9. What type of person identifying information will you be processing (please select all that apply)?

- Personal information
- Pseudonymised personal data

Clinicians directly involved in the patient's care will recruit and consents patients into this study. The Consent Form will contain personal information (patient's name). This will be stored in a locked cabinet in a locked room in an NHS hospital (Trafford General Hospital/Manchester Royal Infirmary/Wythenshaw Hospital). Only the clinicians will have access to the Consent Forms.

Once consented, the clinician will assign a trial ID to that patient. This trial ID will be used on the sample of fluid sent to The University of Manchester. The clinican will also fill in a document containing information about the individual's age, sex and clinical diagnosis under the trial ID. This paper copy will also be kept in a locked cabinet in a locked room in one of the above-named NHS hospitals - again, only accessible to the clinicians. This information will be transcribed into an electronic document by the clinician (on the University of Manchester Research Data Storage Service (Isilon)) for researchers at the University to be able to match the pseudo-anonymised tissue sample to the participant's age, sex and diagnosis.

A second folder will be created in the Research Design Service for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

10. Please provide details of how you plan to store, protect and ensure confidentiality of the participants' information as stated in the question above.

The Consent Form and Patient Data Form will be stored in locked cabinets in a locked room in an NHS hospital (Trafford General Hospital/Manchester Royal Infirmary/Wythenshaw Hospital). Only the clinicians involved in the direct care of the patient will have access to these forms and thus only the clinicians with access to both forms will be able to match the patient's information to their name on the consent form using a pseudo-anonymisation key. The key will also be stored in a locked cabinet in a locked room in one of the hospitals.

The pseudo-anonymous data from the Patient Data Form will be transcribed into an electronic document by a clinician. The 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 and the clinicians will have access to this document, via a password protected interface.

A second folder will be created in the Research Design Service for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder, via a password protected interface. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

Samples of joint fluid removed during treatment will be labelled by the clinician using only the trial ID. Thus, researchers at the

University will be able to match the pseudo-anonymised information in the electronic document (age, sex, clinical diagnosis) 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.

11. If you are storing personal information will you need to keep it beyond the end of the project?

- No

12. Sharing person identifiable information can present risks to participants' privacy, researchers and the institution. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester? This includes using 3rd party service providers such as cloud storage providers or survey platforms.

- No

13. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

14. Are you planning to use the personal information for future purposes such as research?

- No

No data collected for this research will be used for future research purposes. All data will be destroyed at the end of the study.

15. Who will act as the data custodian or information asset owner for this study?

Leela Biant

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

26/04/2019

Project details

What is the purpose of your research project?

Identify proteomic biomarkers of frozen shoulder in synovial fluid.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

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 extraction,storage and analysis human tissue (synovial fluid). 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

Who will be responsible for data management?

Principle Investigator - Professor Leela Biant

Some day to day tasks associated data management (such as quality control, digitisation, security and organisation of the data) will be carried out by members of the research team and cliniciains involved in the direct care of the patients.

The clinicians (led by Mr Ananthan Ebinesan) will be responsible for collecting the tissue samples and collecting and securely storing the demographic data (sex, age, diagnosis). They will also be responsible for pseudo-anonymising the data and digitising the demographic data into a secure spreadsheet on University of Manchester research storage files. They will also be responsible for quality control and organisation of the data they collect.

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

What resources will you require to deliver your plan?

Access to a lockable filing cabinet and room for storage of the hard copies, 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 research team will be required to train the clinicians on how to collect and store the data appropriately in the hospital.

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

Data Collection

What data will you collect or create?

Consent Form: Name, Date - This will be created in paper format only (3 copies - one for patient, one for patient notes and one for trial file)

Patient Data Form: Age, Sex, Clinical Diagnosis, Trial ID - The original copy will be on paper and will be filled out by the clinician after consent is taken. This information will then be digitised by the clinician in an excel sheet in a folder saved on the University of Manchester's reccommended research storage service.

Synovial Fluid Sample: Trial ID, 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 in the excel spreadsheet.

Proteomic analyses will be carried out on the synovial fluid samples at The University of Manchester. The results from these analyses will be stored in a folder on the University of Manchester's reccommended research storage service. Only the researchers (not the clinicians) will have access to this folder.

How will the data be collected or created?

Eligible patients will be identified by consultant orthopaedic surgeons. Patients undergoing an invasive clinical or surgical procedure on the shoulder will be eligible for the study as it will be possible for the surgeon to remove a sample of joint fluid during the routine procedure.

Prior to the procedure, the clinician will discuss the study with the patient. If the patient is willing to donate a sample of synovial fluid to the University, the patient will be asked to sign a consent form. The clinician will then assign a trial ID to the patient.

During the routine treatment, the clinician will remove a sample of synovial fluid from the shoulder joint and label this with the date and trial ID. This will be done using standardised methods. The clinician will also fill in a Patient Data form which will include the ID, age, sex and clinical diagnosis related to the sample. The paper copies of these data and consent forms will then be stored in locked filing cabinets in locked rooms at the hospital.

A member of the research team will pick up the sample(s) on the day of the procedure and transport these to the University of Manchester, where discovery proteomic techniques will be used to analyse the samples. 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.

The clinician will enter the Patient Data into an electronic excel document on the University of Manchester Research Data Storage service. University of Manchester researchers will then be able to access this pseudo-anonymous data and link the samples received to the age, sex and clinical diagnosis of the individual. The data entry will be validated by another clinician at a later date to minimise human error in transcribing the paper data to the electronic spreadsheet.

The results from the proteomic analyses will be stored in a folder on the University of Manchester's reccommended research storage service. Only the researchers (not the clinicians) will have access to this folder.

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 CRFs. This will be maintained by the clinicians, and will also be organised as per current GCP guidelines and recommendation.

Documentation and Metadata

What documentation and metadata will accompany the data?

An explanation of how researchers can access the data collected during this study will be given in the trial 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), data analysis 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.

The Proteomics standards outlined by MIBBI (Minimum Information for Biological and Biomedical Investigations) will be adhered to.

Ethics and Legal Compliance

How will you manage any ethical issues?

Each individual in this study will be given a unique number to pseudo-anonymise their data. Only clinicians involved in the direct care of the patients will have access to identifiable data, and only these clinicians and researchers named on the approved protocol will have access to the pseudo-anonymised data. The data will be kept no longer than is necessary.

The study will be referred to a local NHS Research Ethics Committee for approval (via the Integrated Research Application System), as participants will be recruited from local hospitals (Trafford General Hospital, Manchester Royal Infirmary, Wythenshaw Hospital). The study will not commence until approval has been granted.

Written and verbal consent will be taken from each patient prior to their inclusion in the study. Participants will be free to withdraw from the study at any time by informing their clinician verbally or in written form. 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. If an individual wishes to withdraw, the clinician will use the pseudo-anonymisation key to identify the individual's ID. The clinician will then inform the researchers at the University of Manchester which sample to destroy.

The study data will be kept for 10 years as a non-patient identifiable database on The University of Manchester Research Data Service. 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 an NHS hospital. The chief investigator, sponsor representative and study monitors will have access if required.

We intend to disseminate this research in peer-reviewed scientific journals, conference presentations and by publications on websites. No patient identifiable information will be published.

Summary:

- There are clear processes for pseudo-anonymising data to protect confidentiality of participants when needed
- Patient identifying information will be stored separately and securely from data relating to research participants
- Secure transfer of data e.g. demographic data from hospitals to the University’s Research Data Storage (RDS) service.

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

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

Storage and backup

How will the data be stored and backed up?

The hard copies of data will be stored in a locked filing cabinet in a locked room at the hospital at which the patient was recruited. This data will be backed up electronically as soon as possible by the clinician.

All electronic data will be stored on the University of Manchester Research Data Storage system which is backed up every day and is secure. Two discreet folders within the Service will be used. One folder will be created for depositing the pseudo-anonymised data collected in the clinic (sex, age, diagnosis) - the clinicians and researchers will have access to this folder. A second folder will be created for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

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

How will you manage access and security?

Only researchers listed in the protocol as study researchers and clinicians in the direct care of the patients will be given access to the pseudo-anonymous data and samples. The key for the hard copies of data and consent forms will be kept in a location only known to clinicians involved in the direct care of the patients.

All electronic data will be stored on the University of Manchester Research Data Storage system which is backed up every day and is secure. Two discreet folders within the Service will be used. One folder will be created for depositing the pseudo-anonymised data collected in the clinic (sex, age, diagnosis) - the clinicians and researchers will have access to this folder. A second folder will be created for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

Access to each above-mentioned folder will be restricted to the clinicians and/or 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

Which data should be retained, shared, and/or preserved?

The study data will be kept for 10 years as a non-patient identifiable database using the encrypted University of Manchester Research Data Service. One folder will be created for depositing the pseudo-anonymised data collected in the clinic (sex, age, diagnosis) - the clinicians and researchers will have access to this folder. A second folder will be created for the storage of all data analysis and results on the pseudo-anonymised samples. Only the researchers will have access to this folder. The clinicians will not have access to this folder as it would be possible for them to breach patient confidentiality by using the pseudo-anonymisation key to find a specific patient's results from the analyses.

The pseudo-anonymised data will be shared on Mendeley by the researchers - 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.

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

The study data will be kept for 10 years as a non-patient identifiable database on an encrypted university computer.
The master file and hard copies of data will be kept for 10 years in secure locked storage on hospital site. The hospital is well equipped for securely preserving hard copies of data for long periods of time, given they hold patient notes under these conditions.
The chief investigator, sponsor representative and study monitors will have access if required.

Data Sharing

How will you share the data?

The raw data will not be shared with anyone outside of the University of Manchester. Pseudo-anonymised 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.
The outcomes of this study will be over many years and will not be specific to any one patient. Direct feedback to each patient will therefore not be provided. The long term gain in developing better diagnostics and treatments for frozen shoulder arising from the patients generosity in donating synovial fluid will be informed to each patient prior to them giving consent.
This research 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.

Are any restrictions on data sharing required?

Only pseudo-anonymised data will be shared to the public.