Plan Overview

A Data Management Plan created using DMPonline

Title: What is the relationship between serum concentration of GlycA, lipid profile and muscle strength in a population with osteoarthritis of the knee?

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Project abstract:

The role of exercise in patient with knee osteoathritis to reduce levels of systemic inflammation has not been previously reported. Utilising a novel inflammatory mediator GlycA we will attempt to determine their relatioship.

In addition, the changes in muscle strength and functionality as well as lipid profile.

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Copyright information:

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What is the relationship between serum concentration of GlycA, lipid profile and muscle strength in a population with osteoarthritis of the knee?

Data description

What data will you create?

Quantitative data will be collected using Microsoft Forms to survey no more than 60 participants. This will be downloaded onto an Excel spreadsheet (.xsls) and saved on UoN OneDrive. Excel files will be exported into SPSS (.sav) for analysis.

Data collection / generation

What are your methodologies for data collection / generation? How will you ensure data quality? What data standards will you use?

- Individuals who agree to attend for a clinical assessment will participate for two appointments. This appointment will last approximately 2-3 hours.
- They will be seen at the Academic Rheumatology Unit, Clinical Sciences Building, Nottingham City Hospital and will be asked to come between 8.00am and 10.00am without having had breakfast or any drink other than water.
- Transport (taxi) will be arranged if required and any travel expense will be reimbursed.
- Our Research Nurses will get a 15ml blood sample from the participant and also ask the participant to provide a urine sample.
- Once blood and urine samples have been collected participants will be offered a light breakfast and drink refreshment before a brief assessment to confirm medical history and current medications. Questionnaires such as WOMAC, MSK-HQ and Numeric VAS will be collected.
- Physiological measurements such as 30 seconds sit to stand (30CST), time up and go (TUG) and Muscle strength assessment will be taken at this point.
- Diagnostic ultrasound of most painful knee will be conducted.
- Quantitative sensory testing to test the sensitivity to mechanical pressure and pain.
- Participants will be asked if they wish to donate a faecal sample and if they agree they will be given a collection kit to take home, which will be shipped back by post.
- Participants will be shown how to wear actigraphy device and will be familiarised with the equipment. Each participant will take one device with them, therefore, their sleeping pattern can be assessed.
- Participant will be expected to login to online exercises portal on daily basis and complete the exercises which consist of 30 minutes of exercises and some educational videos.

Data storage and security

Where and how will data will be stored, backed-up, transferred, and secured during the active phase (short to medium term) of research? When and how will you delete the data once the project is completed?

Each participant will be assigned a study identity code number, and this will be used on the study forms as well as other trial documents and the electronic database. This will be a randomly generated unique participant identifier. An additional identifier will be sued to allow validation of participants ID and prevent number being transposed. This additional identifier will consistent of participant’s initials at the end of unique participant identifier number.

Study forms will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant’s name, date of birth, local hospital number or NHS number, and Participant Study Number, to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required.

Study forms shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded in a Study Personnel Log. All paper forms shall be filled in using a black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

The Chief or local Principal Investigator shall sign a declaration ensuring the accuracy of data recorded in the study form.

Each participant will be assigned a unique study identification code number for use on the samples, consent forms and other study documents and the electronic database.

Source documents shall be filed at the investigator’s site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A study form may also completely serve as its own source data.

Data management, documentation, and curation

What are your principles, systems, and major standards for data management and creation? What metadata and documentation will you keep?

Source documents shall be filed at the investigator’s site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A study form may also completely serve as its own source data.

The study form and all source documents, including progress notes and copies of laboratory and medical test results, shall be made be available at all times for review by the Chief Investigator, Sponsor’s designee and inspection by relevant regulatory authorities.

All trial staff and investigators will endeavour to protect the rights of the trial’s participants to privacy and informed consent and will adhere to the Data Protection Act, 1998. The study forms will only collect the minimum required information for the purposes of the trial. Study forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). The computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). Information about the trial in the participant’s medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format

Ethics & Privacy

Are there any ethical or privacy related issues associated with your data?

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made, that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms, and participant and GP information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately notifying the REC as soon as possible and approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately, and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social Care, 2005.

Roles & responsibilities

Who will be responsible for managing data, data security, data quality, and data security both during the award and post-award?

Dissertation supervisor Ana Valdes is the data owner and has responsibility for the data as overseer of the project. The data steward is Bernardo Brandao who is responsible for the day to day handling and security of data. All project members are required to follow the DMP. All project members are responsible for their own use and management of data.

IPR

Who will own the copyright and IPR of any data that you will collect or create? If you are planning to use existing data as part of your research, do any copyright or other restrictions determine its use?

Copyright & IPR for all project research data is owned by University of Nottingham.