Improving the Diagnosis and Early referral of patients with AxiaL spondyloarthiritis: BACK Pain referral pAthway from Community to Specialist care (IDEAL- BACKPACS)

IRAS ID 339400

Participant Information Sheet

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1. You are invited to take part in our research study

- The IDEAL – BACKPACS study is looking to find better ways to diagnose an inflammatory back condition called axial spondyloarthritis (axSpA)
- This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part
- Please take time to read this information and ask us if there is anything that is not clear to you or you would like more information
- It is entirely your decision whether to take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way

2. A summary of the study

The IDEAL – BACKPACS study focuses on finding better ways to diagnose axial spondyloarthritis (axSpA) (formally known as ankylosing spondylitis [AS]). AxSpA is an inflammatory condition affecting approximately 270,000 people in the UK, causing pain, stiffness and damage to the spine, pelvis and joints. Symptoms, such as back pain, start in early adulthood and get worse with time. Currently it takes 5-8 years for people to get a diagnosis. Back pain is a common symptom and only a minority of people with back pain have axSpA It is therefore difficult for General Practitioners (GPs) to tell if back pain is due to inflammation. Effective treatments for axSpA are available. If axSpA is diagnosed earlier, then these treatments can be more beneficial and axSpA related health problems may be reduced.

We want to help GPs identify patients with inflammatory back pain to enable early diagnosis and faster access to treatment. We will design and test a new tool, to be integrated into GP computer systems, to help GP clinicians decide if a patient needs to be referred to a specialist, and the impact of this on the patients' wellbeing and delays in diagnosis. We will gain information from patients with back pain (from clinical assessment, blood test, x-ray (if you are aged 18 or over) and MRI) that might be caused by axSpA to help us design this tool.

The new tool developed will be compared with existing tools to see if it is able to identify people with axSpA better and faster.

If you agree to take part, you will be asked to complete an online questionnaire and attend **two hospital visits at a local rheumatology research clinic near to you.** Visit 1 involves a clinical assessment, blood test and x-ray

of your lower back and pelvis. Visit 2 involves an MRI scan of your back and pelvis. Please see section 6 for more details.

3. What is the purpose of the study?

Our aim is to make it easier and faster for General Practice clinicians to identify patients who may have axSpA, through designing and testing a new tool which will be integrated into GP computer systems.

We will speak with patients, the public and carers, as part of a wider programme of work, to make sure this new method is acceptable, useful and practical. We want to make it easier and faster for people with back pain to get the right care from Rheumatology services.

4. Why have I been invited to take part?

You have been invited to take part as you are aged 16-50 years old and have visited your GP for your long-term back pain (more than 3 months). We are inviting up to 900 people with long-term back pain, like yourself, to take part in this study.

5. Do I have to take part?

It is up to you whether or not you take part in the study. Even if you agree now, you are free to withdraw at a later date if you wish. We will talk to you about the study and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.

6. What would taking part involve?

Eligibility phone or video call

If you agree to be contacted about the study, you will receive a telephone, or video call, from the research team at your local hospital. The researcher will ask if you would like to take part in the study, answer any questions and confirm that you are eligible to participate.

Consent

If you decide to take part, you will be given a personal link to complete an online consent form.

The researcher will arrange an appointment to attend the rheumatology research clinic at your local hospital. This details of this visit are described below (visit one).

Completing a research questionnaire

We will ask you to complete a questionnaire online at the beginning of the study so we can see how your back pain is affecting you. This questionnaire might take around 25 minutes to complete.

Visit one

You will be sent details of your appointment once a date is confirmed. On the day of the appointment at your local hospital you will be met by a researcher who will guide you through all the assessments to be performed and confirm you are happy to continue with the study.

- The appointment will include a **clinical assessment** that will last around 30 minutes. The assessment will look for signs of arthritis, measure your mobility and ask about your personal and family history relevant to the condition.

- We will ask whether your pain eases after taking a non-steroidal anti-inflammatory medication (NSAID) such as ibuprofen for 7 days. If this is unclear, and it is safe for you to do so, the clinician will ask you to take a 7 day course of an NSAID medication. You will then be contacted at the end of the 7 days to ask whether the NSAID medication had any effect on your back pain.

- You will also provide a **blood sample**. The blood sample will be used to look for a genetic marker related to spine inflammation HLA-B27 (human leukocyte antigen B27) and CRP (c-reactive protein), high levels of which can show there is inflammation present in your body. The blood sample will be destroyed after analysis.

- You will also be asked if you would allow for samples of your blood to be stored for future research (this is optional and is part of a separate study).

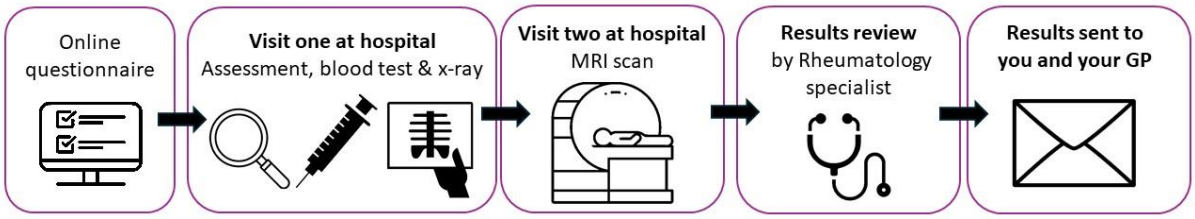
- **If you are aged 18 and over**, **an x-ray** of your sacroiliac joints will be taken. These are the joints between your pelvis and lower spine.

- The researcher will arrange the second visit which will be for the MRI Scan.

Visit two

- You will attend the final visit at your local hospital for your **MRI scan**.

- It is important that you do not take any NSAID medication (eg ibuprofen, diclofenac, naproxen, meloxicam, etoricoxib, etodolac and nabumetone) for **7 days before your MRI** as these can make the scans less clear. You can take other pain killers such as paracetamol if needed. The MRI should last around 30 minutes and will be of your sacroiliac joint and whole spine. You can restart your NSAID medication after the scan.



The results from your assessment, blood test, x-ray and MRI scan will be reviewed by a specialist who will make a decision whether your back pain is due to inflammation (i.e. you are highly likely to have axSpA) or not inflammatory (i.e. not due to axSpA). They will write to you and your GP and offer advice of the next steps for your treatment/care pathway.

We will inform your GP about your participation in this study.

Your name and telephone number will be shared with Esendex, our text messaging provider and their sub-processors, and will be used to send you text message reminders about the study and study questionnaires whilst you are participating in the study. Esendex will hold this information securely and delete it from their records at the end of the study.

We require contact to be maintained with you throughout the study, to arrange appointments and send you

the results of the investigations at the end of the study. With your consent, we may send you further brief follow-up questionnaires (up to 3 years) [subject to additional funding – you will be informed if this will go ahead once funding has been confirmed.]. We will ask your permission to send you newsletters, final study results and information about future studies, this contact is optional.

As a thank you, if you attend the study visits, you will receive a £15 shopping voucher.

7. What are the possible benefits of taking part?

Taking part in the study may not directly benefit you, but the information we collect from this study may help us to treat people with axSpA, and understand more about axSpA in the future.

Taking part in this study will include having an assessment in hospital with a rheumatology specialist, an x-ray (if aged 18 or over) and an MRI scan. Once all your results have been reviewed by a specialist doctor, you and your GP will receive a letter with the results along with advice leaflets. The letter will state whether you are likely to have axSpA, or whether your back pain is likely to be non-inflammatory and due to other causes.

8. What are the possible disadvantages and risks of taking part?

You will be asked to complete a questionnaire which may take around 25 minutes to complete and be required to travel to the hospital for the visits described in section 6.

You may experience discomfort from the blood test, however this will not be any greater than you would experience during a standard blood test for other purposes.

As part of the study, you will be asked to have a MRI scan and an x-ray (if 18 years or older). MRI and x-ray are widely used in medical practice and are considered safe.

MRI uses radio waves similar to those used in radio and TV transmission. These have a much lower energy than X-rays and as such are considered biologically safe. We will be following strict national safety guidelines which are designed to prevent the theoretical and rare hazards of MRI such as burns and electric shocks. There is no evidence to suggest that MRI is harmful during pregnancy, but the regulatory body (Medicines and Healthcare products Regulatory Agency: MHRA) advises against scanning pregnant women; we have decided not to test for pregnancy routinely, but if you think you may be pregnant you should not be scanned. Please let the study team know if you become pregnant during taking part in the study. You will be withdrawn from further assessments in the study.

MRI uses a powerful magnet so cannot be performed if you have a heart pacemaker, certain implants or any previous injuries which have left iron/steel in your body; this will be checked in a safety check before you enter the scanner room. The magnetic fields from MRI are not known to cause any adverse effects. You will be asked to lie flat and still during the scan. The MRI scan may be noisy and there may be loud tapping noises. You can be provided with ear protection. Some people may feel claustrophobic in the confined space of an MR scanner if you know that you are claustrophobic, you should not take part. During the scan, you will be able to communicate with the scanning staff via an intercom and will be given a hand-held buzzer, which can be used to alert staff and end the scan at any time.

Before the MRI scan you will be screened by a radiographer to make sure it is safe for you to have a scan. The radiographer will ask you a series of questions and if he/she believes you are suitable will ask you to sign a separate consent form. The MRI scan may show incidental findings that could lead to further investigations with no outcome or benefit.

For participants aged 18 and over who will have an x-ray
If you take part in this study you will have an X-ray of your sacroiliac joints. This may be extra to those that you would have if you did not take part. This procedure uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add up to only 0.001% chance of this happening to you.

These scans are performed routinely in NHS practice, and they will be performed in the standard way, by NHS radiographers, in this study. The scans will be reviewed by a consultant radiologist and if a significant unexpected abnormality is found, your GP will be contacted by the hospital team.

9. What if there is a problem?

If you have concerns or questions about any aspect of this study, you should ask to speak to the local researchers. Their contact details are at the end of this information sheet.

If any questions remain you can contact the study coordinating centre:
Tel: 0115 7487106, Email: ideal@nottingham.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS).

In the event that something does go wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

10.What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you would like to withdraw, contact your local researchers or the Nottingham Clinical Trials Unit (NCTU) study team and they can organise this for you. Their contact details are at the end of this information sheet. If you withdraw the information collected will not be erased and this information may still be used in the project analysis.

11.How will information about me be used?

The sponsor and research team, including the Nottingham Clinical Trials Unit (part of the University of Nottingham), and at University College London will need to use information from you, your medical records and your GP for this research project. This information will include your initials, NHS number, name and contact details. The researchers will use this information to do the research or to check your records to make sure that the research is being done properly.

Your x-ray images and MRI scans will be stored securely using a digital database known as XNAT at University

College London and will be interpreted as part of the IDEAL study. In addition, they will be analysed for studies related to the main IDEAL programme study, including studies for the development of new algorithms helping to improve the identification of inflammation from medical imaging tests. We plan to keep these images for a period of up to 20 years to enable future research that could benefit other people in the future. Storage of your images for this extended period is optional and, if you do not consent to this, your scans will be disposed of securely along with other information in the study (see section 12)

People who do not need to know who you are will not be able to see your name or contact details, your data will have a code number instead.

All information about you will be kept safe and secure.

Once the study has finished, some of the data will be kept so the results can be checked and you can be told what happened in the study (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the study.

We may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data shared in this way will be anonymised.

12.What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

After 7 years your data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with your condition that you may be interested in taking part in. You will also have the option to take part in future research using your data saved from this study. This will include future research using the medical images (x-ray and MRI scans) acquired during this study. If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the study.

13.Where can you find more about how your information is used?

You can find out more about how we use your information:

- at **www.hra.nhs.uk/information-about-patients/** and **www.hra.nhs.uk/patientdataandresearch**
- reading our privacy statement at https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx
- **http://www.nctu.ac.uk/data-protection/data-protection.aspx**
- by asking one of the research team
- by sending an email to ideal@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on 0115 7487106

14. Who is organising and funding this study? How has it been reviewed and approved?

The study is being organised by the University of Nottingham (the sponsor) and coordinated by the NCTU. The funding for the study is provided by the National Institute for Health and Care Research (NIHR). All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a Research Ethics Committee (Yorkshire & The Humber - Sheffield Research Ethics Committee, reference 24/YH/0188).

Patients who have previously been treated for axSpA have helped us plan and design this study, including reviewing documents. Patients' representatives are also involved in the teams that oversee the running of the study.

15. What if relevant new information becomes available?

Sometimes we get new information about your condition during the study. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the study he/she may ask you to sign a new Informed Consent Form.

16. What will happen to any samples I give?

The blood sample that we take for this study will be analysed at the local hospital laboratory and the results of the blood test will be recorded by the research team. The sample will then be destroyed and no further tests will be performed on the blood sample. The results will be shared with the clinical team and research team running the study.

At the time of your blood test you may be asked if you'd be interested in providing a sample of blood for additional studies, this is optional and will be discussed with you at the visit. If you agree the researcher, working on behalf of the other study team, will ask you to read another information sheet and sign an additional consent form. If you consent to this, some of your medical information we are collecting for IDEAL BACKPACS, e.g. if you are diagnosed with axSpA, will be shared with the other study team to help with these studies.

17. What happens at the end of the Study?

When the study ends, your healthcare will continue as normal. If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

18. How to contact us

Contact details of your local care team who will be your main point of contact for the duration of the study to be provided following expression of interest.

You can contact the central IDEAL-BACKPACS study team based at Nottingham Clinical Trials Unit on;

Phone: 0115 7487106
Email: ideal@nottingham.ac.uk

Address: Nottingham Clinical Trials Unit, Applied Health Research Building, University Park, University of Nottingham, Nottingham, NG7 2RD