Taking aim at delays to arthritis treatment

Submission date	Recruitment status	Prospectively registered
29/12/2021	No longer recruiting Overall study status	[X] Protocol
Registration date		Statistical analysis plan
14/03/2022	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
08/04/2025	Surgery	

Plain English summary of protocol

Background and study aims

This study will determine whether artificial intelligence (AI) can help general practitioners' (GPs') decision-making about which patients with arthritis are referred for hip or knee replacement surgery.

More than 1 in 10 people over the age of 45 have arthritis. This can be associated with significant pain and inability to perform normal activities such as walking, getting dressed or going to the shops. Some have described living with the condition as a state "worse than death". Surgery provides an excellent solution but is not a suitable option for all patients.

Currently GPs often have difficulty deciding which patients with arthritis might benefit from an operation. This leads to many referrals for orthopaedic input and prolonged waiting times for surgery.

Planned AI analysis of routinely collected health information about patients with end-stage hip and knee arthritis will allow for the development of a tool that helps predict who is likely to undergo surgery.

Who can participate?

The study will utilise routinely collected health data from patients aged 16 years and over who have previously undergone routine hip and knee replacement surgery within NHS Grampian.

What does the study involve?

The study will use routinely collected health data to try to build a good picture of who might undergo hip and knee replacement surgery in future.

What are the possible risks and benefits of participating?

Development of the tool will help improve future referral pathways, ensuring those likely to benefit from surgery are seen promptly and efficiently. This should see reduced waiting times that helps those needing surgery to get back on their feet again quickly. The risks of participation are very small as there is no direct patient contact. All patient information is managed in a specialised safe environment designed to ensure minimal risk of any details being leaked.

Where is the study run from?

The Centre for Health Data Science within the University of Aberdeen (UK)

When is the study starting and how long is it expected to run for? August 2020 to March 2024

Who is funding the study?
The Chief Scientist Office (CSO) in Scotland (UK)

Who is the main contact?

- 1. Mr Luke Farrow, luke.farrow@abdn.ac.uk
- 2. Prof. Lesley Anderson, lesley.anderson@abdn.ac.uk

Study website

https://www.abdn.ac.uk/achds/research/archery-263.php

Contact information

Type(s)

Public

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CAF/21/06

Study information

Scientific Title

Al to Revolutionise the patient Care pathway in Hip and knEe aRthroplastY

Acronym

ARCHERY

Study objectives

Primary objectives:

- 1. Develop a cohort of patients referred by GPs regarding the assessment of suitability for hip or knee replacement and collect laboratory, clinical and imaging data from NHS Grampian via the Grampian DaSH.
- 2. Determine demographic, clinical and/or imaging characteristics influential in the selection of patients to undergo hip or knee arthroplasty, with the development of a tested and validated patient specific predictive model to guide arthroplasty referral pathways.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/10/2021, North Node Privacy Advisory Committee (NNPAC, University Office, King's College, Aberdeen, AB24 3FX, UK; +44 (0)1224 272000; nnpac@abdn.ac.uk), ref: 6/091/21

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Patients undergoing primary elective hip and knee arthroplasty

Interventions

The project will be conducted through two linked work packages designed to deliver on the project objectives.

Work package 1 – Definition of a Grampian regional data source with the establishment and validation of a linked orthopaedic health care dataset utilising routinely collected data

The first work package will utilise ready to access local regional data from NHS Grampian that combines routine administrative data systems with enriched local data. Similar linked datasets have been used extensively by the team at the Aberdeen Centre for Health Data Science, within which the candidate will be hosted. Techniques for data access and processing are described in detail later in the protocol. Patient demographic information (SMR01), prescribing and dispensing (PIS), laboratory data (Apex Haematology/Biochemistry), COVID data, theatre records (Centricity OPERA) and patient-reported outcome measures (PROMs) (Local PROMs database) will be used to develop core algorithms using combinations of relevant clinical codes (e.g. ICD-10 or OPCS-4). Standard Morbidity Record 01 (SMR01) and theatre records (Centricity OPERA) will provide the main resource for identifying joint replacement through relevant ICD-10 codes. Unstructured (e.g. free text) information in clinical letters and radiology image data will be used to validate and enhance these detailed characterisations. Risk factors and outcome measure algorithms will also be developed and validated against electronic clinical records.

Clinical knowledge of key parameters involved in surgeon decision making regarding the determination of who will undergo arthroplasty operations, as well as a planned systematic review, will aid variable selection. Given the standardisation of referral through the national Scottish Care Information (SCI) Gateway system and the widespread similarities in approach to joint replacement selection throughout the UK, the use of Grampian regional data should

provide a model that is widely applicable. Furthermore, the close links between iCAIRD sites in Aberdeen and Glasgow will be utilised to ensure that all data sources utilised have relevance regarding potential future suitability for national application.

Subsequent operationalisation and automation of these techniques will allow for systematic and reproducible approaches to characterising the key clinical features of the data relevant to orthopaedics. Algorithms created will be then scaled and utilised to appropriately categorise and construct a linked dataset that covers all relevant hospital episode data covering patients referred to orthopaedics to be used in the subsequent work package.

Work package 2 – Determination of variables influential hip and knee arthroplasty selection, achievement of a meaningful improvement in patient-reported outcomes, and avoidance of complication post-operatively with subsequent patient-specific model development.

Utilising the cohort developed in WP1, probabilistic and classification machine learning will be employed through statistical analysis software (Rstudio, Python and Tensorflow) to predict whether or not a patient would be selected to undergo surgery based on pre-operative clinical data (including imaging data/reports and clinical letters [through natural language processing], patient healthcare information and patient-reported outcome measures).

The machine learning models will utilise data from the predictive variables isolated from preoperative routine healthcare data described in WP1. Pre-trained convolutional neural networks (a type of machine learning categorised as deep learning) will be used for X-ray images in order to significantly increase generalisability, with X-ray images providing the foundation for model creation. To facilitate model training, development and internal validation the researchers will use k-folds cross-validation, allowing all data to be used for testing and internal validation purposes without sample attrition.

Intervention Type

Procedure/Surgery

Primary outcome measure

Dichotomous prediction of whether a patient would be selected to undergo hip or knee arthroplasty based on their baseline electronic health record data at the time of the first orthopaedic clinical review

Secondary outcome measures

- 1. Probabilistic prediction of arthroplasty selection based on baseline electronic health record data at the time of the first orthopaedic clinical review
- 2. Probabilistic prediction of Minimal Clinical Important Difference achievement in EQ-5D and Oxford Hip/Knee Scores at 1-year postoperatively
- 3. Probabilistic prediction of the risk of adverse healthcare outcomes (acute kidney injury /hyponatraemia/cardiovascular event/venous thromboembolism/reoperation/readmission/mortality) at 30 days and 1-year postoperatively

Overall study start date 06/08/2020

Completion date

01/03/2024

Eligibility

Key inclusion criteria

- 1. Aged ≥16 years
- 2. Have undergone either elective primary hip replacement or primary knee replacement
- 3. Surgery performed within NHS Grampian between January 2018 and January 2022

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

2000

Total final enrolment

25126

Key exclusion criteria

- 1. Individuals who have opted out of data sharing at either a local or national level
- 2. Individuals who have undergone revision hip and knee arthroplasty, arthroplasty at another site or unicompartmental knee replacement
- 3. Individuals who have undergone hip or knee replacement for trauma (hip fracture or distal femoral fracture)
- 4. Individuals who have undergone operative management outside of NHS Grampian

Date of first enrolment

01/03/2022

Date of final enrolment

01/06/2023

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Clinical Research Facility - University of Aberdeen

Polwarth Building Foresterhill Aberdeen United Kingdom AB25 2ZD

Sponsor information

Organisation

University of Aberdeen

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Sponsor type

University/education

Website

https://www.abdn.ac.uk/clinicalresearchgovernance/research-development/index.php

ROR

https://ror.org/016476m91

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)

Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal, with associated presentation of the produced work and major national and international conferences. The protocol will be published shortly in a peer-reviewed open-access journal. This protocol will include details of the study data management plan and data flow information.

Intention to publish date

01/08/2024

Individual participant data (IPD) sharing plan

Individual patient data will not be shared but the metadata utilised in the development of the proposed clinical prediction models will be shared on an open repository (GitHub) in line with good practice on reproducible science methodology.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
<u>Protocol</u> <u>article</u>		11/05 /2022	12/05 /2022	Yes	No
Other publications	Managing class imbalance in the training of a large language model to predict patient selection for total knee arthroplasty: Results from the Artificial intelligence to Revolutionise the patient Care pathway in Hip and knEe aRthroplasty (ARCHERY) project	27/02 /2025	03/03 /2025	Yes	No
Results article		01/07 /2024	08/04 /2025	Yes	No