ISRCTN95817502 https://doi.org/10.1186/ISRCTN95817502

Earlier identification and enhanced understanding using three-dimensional images in the diagnosis of inflammatory arthritis

Submission date
02/10/2025

Recruitment status
Recruiting

Registration date
17/10/2025

Overall study status
Ongoing

Last Edited
17/10/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will test a new type of scanner, the Adaptix Ortho350, to see how it compares to regular hand X-rays. It is the first time this scanner will be used with patients. The goal is to find out if this scanner can give better pictures and help healthcare professionals understand disease-related changes in bones and joints more clearly.

Who can participate?
Adult patients with inflammatory arthritis who require X-rays of the hands.

What does the study involve?
Each person will come for one visit that lasts no more than 45 minutes. During the visit, they will have a scan of both hands and fill out a short questionnaire. A specialist Radiologist will look at the Adaptix Ortho350 images and write a report for the team. These scan results will be sent to their usual healthcare team.
Before the scan, the procedure will be explained, and participants can ask questions. They will then sign a consent form. Their medical history will be checked using notes from their care team, which takes about 15 minutes. The scan itself takes around 5 minutes.
After the scan, participants will fill out a short questionnaire about how they felt about the experience. This takes about 10 minutes. Then they can leave. Their regular treatment will continue as normal.
The research team will also look at X-rays taken within 4 weeks of the scan to compare with the ADT images. Doctors will be asked if the ADT helped them make better decisions. No extra visits are needed.

What are the possible benefits and risks of participating?
Participants may help improve future arthritis imaging and care. They receive a new scan that may offer more detail than standard X-rays. Risks are low but include a small additional radiation dose from X-rays and may include mild discomfort during scanning or the sharing of medical data. Participation is voluntary, and regular treatment continues with their usual healthcare team.

Where is the study run from?
The Medical Imaging Centre at St Luke's Campus, University of Exeter, UK.

When is the study starting and how long is it expected to run for?
January 2023 to September 2026.

Who is funding the study?
1. Innovate UK
2. Adaptix Ltd, UK

Who is the main contact?
Professor Karen Knapp K.M.Knapp@exeter.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
348373

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67177, Sponsor ref 23-26-32, Grant Code 10068051

Study information

Scientific Title

Mobile 3D Imaging of Arthritis (Arthritis3D)

Acronym
Arthritis3D

Study objectives
Adaptix Digital Tomosynthesis (ADT) for assessing the joints in patients with inflammatory arthritis will improve visualisation of joints and surrounding bone compared to standard 2D x-ray imaging.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/08/2025, Sheffield REC (Holland Drive, HRA Newcastle, NE2 4NQ, United Kingdom; +44 (0)2071048139; sheffield.rec@hra.nhs.uk), ref: 25/YH/0032

Study design
Feasibility diagnostic accuracy study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Inflammatory arthritis

Interventions
Adaptix 3D x-ray imaging

The study is a prospective, unblinded, comparative feasibility study of ADT imaging compared to standard radiographs, which will trial ADT in a clinical population for the first time.

This is a one-arm trial including participants with inflammatory arthritis. All participants will undergo imaging as usual, with X-rays of their hands. In addition, a 3D image will be undertaken using the Adaptix Ortho350 digital tomosynthesis device. Acceptability of the new imaging will also be assessed using a questionnaire.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adaptix Ortho360

Primary outcome(s)

Diagnostic performance, measured by comparison of ADT imaging to imaging as usual, at the time of clinical imaging

Key secondary outcome(s))
1. Joint space measurement, assessed using ADT and imaging as usual, at the time of clinical imaging
2. Bone density, measured using ADT, at the time of clinical imaging
3. Bone microarchitecture, measured using ADT, at the time of clinical imaging
4. Image quality of ADT compared to projection radiographs using signal-to-noise and contrast-to-noise ratio, at the time of clinical imaging
5. Patient acceptability, measured using an acceptability questionnaire at baseline
6. Clinician acceptability, measured using feedback on image quality at the end of recruitment

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Inflammatory arthritis requiring X-rays of the hands

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Unable to keep hands still for 15 seconds
2. Women who are pregnant or planning to become pregnant
3. Unable to provide informed consent
4. People who do not have sufficient proficiency in English language to read the participant information sheet or provide informed consent

Date of first enrolment
22/09/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
University of Exeter
Medical Imaging Centre
South Cloisters
St Luke's Campus
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EX1 2LU

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
UK Research and Innovation Innovate UK, innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Adaptix Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during this study are not expected to be made available because they link directly to clinical care and form a feasibility trial dataset only.

IPD sharing plan summary
Not expected to be made available