

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/10/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

### Contact name

Prof Karen Knapp

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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

Exeter

United Kingdom

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)**

Technology Strategy Board

**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