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NanoNeedle evaluation study

Submission date
26/07/2023

Recruitment status
No longer recruiting

Registration date
25/09/2023

Overall study status
Completed

Last Edited
09/02/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
People who have sustained an ankle joint injury, which includes an injury to the ankle syndesmosis (a joint where two bones are held together by ligaments), are offered arthroscopic (keyhole) ankle surgery because the injury can make their ankle joint unstable. In this study, keyhole surgery will be undertaken to assess the ankle ligament injury using Nanoscope technology. The Nanoneedle™ is a part of this technology and is a new single-use chip on the tip of a camera system. The aim of the current study is to evaluate the ability of the NanoNeedle™ scope to accurately assess acute ankle syndesmosis injuries compared with standard arthroscopy. Specifically, the aims are to determine the ease of use, arthroscopic field of view and diagnostic accuracy of the NanoNeedle in diagnosing ankle syndesmosis injury and instability

Who can participate?
Adult patients aged over 18 years old with recent acute ankle syndesmosis injury and clinical or MRI evidence of instability

What does the study involve?
The procedure will be carried out under general or spinal anaesthetic, at the same time as the normal operation planned for the ankle injury. The Nanoneedle™ is placed inside the ankle joint through 1 or 2 tiny incisions to provide the surgeons with high-quality images that can be a better alternative to scans like MRIs, this will allow the surgeons to look at the syndesmosis whilst moving the ankle joint. The images will help to assess the ankle for instability and plan subsequent care.

What are the possible benefits and risks of participating?
Currently, there are long delays to investigations such as MRI and it is feasible that the Nanoneedle could be applied in an outpatient setting with the benefit of allowing dynamic assessment for instability, and therefore could reduce the burden of MRI on the NHS.

As with all operations, there is a small risk of complications, and these will be determined and recorded by the surgical team, either in the clinic or via telephone consultations. The risks of surgery will be discussed prior to the operation and the patient, will sign a standard consent form. Whether or not they agree to participate in the study will not have any effect on the development of potential surgical complications. Potential complications from this type of surgery include pain, swelling, stiffness, infection, blood clots, scar problems, nerve or vessel

damage, bleeding and COVID-19. The use of the Nanoneedle will add approximately 5 minutes to the surgical time compared with standard arthroscopy and therefore does not add any significant risks to the standard surgery.

Where is the study run from?
Basingstoke & North Hampshire Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2022 to December 2025

Who is funding the study?
1. Arthrex GmbH (Germany)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Angie Dempster, Angie.dempster@hhft.nhs.uk

Contact information

Type(s)
Principal investigator

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Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
320825

Central Portfolio Management System (CPMS)
56924

Study information

Scientific Title
Prospective evaluation of nanoneedle (Nanoneedle Ankle Syndesmosis)

Study objectives
The current study aims to evaluate the NanoNeedle to assess unstable ankle syndesmosis injuries, compared with the current gold standard assessment which is arthroscopy, including ease of application, and diagnostic accuracy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/04/2023, Yorkshire & Humber – Bradford Leeds REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048083; leedseast.rec@hra.nhs.uk), ref: 22/PR/1674

Primary study design
Interventional

Study design
Interventional diagnosis imaging

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ankle syndesmosis injury

Interventions
This is a prospective study and will evaluate 20 patients with acute syndesmosis injuries requiring arthroscopic assessment and syndesmosis fixation. Suitable patients will be identified by the 3 investigator surgeons.

The evaluation will be conducted in the theatre setting, in patients under general or spinal anaesthesia. Nanoneedle will be used at the start of the procedure to determine:
1. If a standard review of anatomical structures can be undertaken
2. If the injury pattern and instability can be diagnosed

Nanoneedle findings will be correlated with preoperative MRI findings and findings on standard arthroscopy (4mm scope) at the time of surgery.
An agreed proforma with anonymised data will be filled out for each study patient and will be sent to the Hampshire Hospitals Orthopaedic Research Team.

Intervention Type
Other

Primary outcome(s)
Syndesmosis instability measured using NanoNeedle at the point of use

Key secondary outcome(s)
1. Ease-of-use of NanoNeedle compared with ankle arthroscopy measured using data recorded on a proforma at the point of use
2. Field-of-view of NanoNeedle compared with ankle arthroscopy measured using data recorded on a proforma at the point of use

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Adults aged over 18 years old
2. Acute ankle syndesmosis injury with clinical or MRI evidence of instability
3. Time of injury to surgery < 6 weeks
4. Injury patterns including posterior malleolus fractures and Maisonneuve (proximal fibula fracture) injuries)
5. Pre-operative imaging with MRI scan +/- plain radiograph

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Under 18 years of age
2. Ankle fracture requiring distal fibula fixation

3. No preoperative MRI scan
4. Injuries greater than 6 weeks old at the time of surgery

Date of first enrolment
14/07/2023

Date of final enrolment
13/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
England
RG24 9NA

Sponsor information

Organisation
Hampshire Hospitals NHS Foundation Trust

ROR
https://ror.org/04shzs249

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Arthrex GmbH

Alternative Name(s)
Arthrex Medizinische Instrumente GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	27/04/2023	08/09/2023	No	Yes
Protocol file	version 5.0	28/02/2025	09/02/2026	No	No