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CLARITY is a study which aims to improve patient care pathways and to ensure that patients with suspected appendicitis receive the appropriate care that they need

Submission date
20/08/2024

Recruitment status
No longer recruiting

Registration date
03/09/2024

Overall study status
Completed

Last Edited
16/12/2025

Condition category
Digestive System

[_] 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
Appendicitis is a common condition where the appendix, a small part of the bowel, becomes inflamed. If untreated, it usually doesn't get better on its own, so the appendix is often removed through surgery. However, diagnosing appendicitis can be tricky because its symptoms can resemble other conditions. While doctors use blood tests and scans to help with the diagnosis, the way these are used varies across the UK, leading to some patients being misdiagnosed or undergoing unnecessary surgery. In fact, about 20% of people in the UK who have their appendix removed are found not to have had appendicitis after all, which is much higher than in other European countries.

The CLARITY study aims to improve how doctors diagnose and treat suspected appendicitis. The goal is to reduce unnecessary hospital admissions and surgeries by educating doctors on using the best evidence-based strategies to diagnose appendicitis more accurately.

Who can participate?
This study is focused on doctors, so it does not require patients to participate directly. However, patients with suspected appendicitis will benefit from the improved care pathways being tested.

What does the study involve?
For patients with suspected appendicitis, there won't be any changes to their care, and they won't need to attend extra appointments or fill out surveys. The study is testing an educational intervention for doctors, which means the focus is on improving how doctors make decisions about diagnosing and treating appendicitis.

What are the possible benefits and risks of participating?
There are no risks for patients involved in this study since their usual care won't change. The potential benefit is that the study could lead to better diagnosis and treatment for appendicitis, reducing unnecessary surgeries and hospital stays.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
May 2024 to January 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Dion Morton, dion.morton@uhb.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334172

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_24-022

Study information

Scientific Title
SurgiCaL educAtion to Reduce IncorrecT care pathwaYs and enhance patient outcomes in right iliac fossa pain

Acronym
CLARITY

Study objectives
CLARITY is a study which aims to improve patient care pathways and to ensure that patients with suspected appendicitis receive the appropriate care that they need. We will do this by trying to reduce unnecessary admissions for appendicitis in the United Kingdom. CLARITY will test whether educating doctors who diagnose and treat appendicitis prompts them to use the best evidence strategies to diagnose appendicitis correctly. In turn this may enable doctors to reach the correct diagnosis earlier and to use admissions or surgery in patients that require them.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/05/2024, HRA and Health Care Research Wales (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8000; contact@hra.nhs.uk), ref: 24/HRA/2214

Study design
Multicentre parallel cluster randomized controlled trial with an effectiveness-implementation design

Primary study design
Interventional

Study type(s)
Diagnostic, Efficacy

Health condition(s) or problem(s) studied
Improve patient care pathways in patients with suspected appendicitis

Interventions
The intervention is the CLARITY accurate diagnosis package, which is made up of three components: the evidence based education programme (EBP), an implementation checklist and local implementation strategies. The EBP is considered the main component of our intervention and will be delivered using a digital education platform to intervention sites.

There are two study arms: intervention and control. Randomisation of sites is carried out on Redcap using a 1:1 minimisation algorithm.

Intervention arm
Sites randomised to the intervention arm receive access to our intervention, the CLARITY evidence-based education programme. Doctors and clinicians within the acute surgical team, are encouraged to carry out the programme in a 4-week training period. This is followed by 8 weeks of data collection, during which routine data will be gathered for all consecutive patients aged 16-39 years who are referred to general surgery with right iliac fossa pain. The follow up is for 30 days, starting from the date of index admission or attendance to hospital. There is no patient level intervention.

Control Arm
Sites randomised to the control arm do not receive the intervention and continue with their routine practice. They are asked to complete an 8-week data collection period and 30 days follow up.

Intervention Type
Behavioural

Primary outcome(s)
Non-operative admission rate (NOAR) defined as the proportion of patients admitted overnight with right iliac fossa pain who did not undergo an operation. Measured by review of patient notes at 30 days follow up. Measured by the patient's admission and discharge on different dates without any record of operative intervention during their stay. This excludes patients that are subsequently admitted to hospital with missed appendicitis and readmissions.

Key secondary outcome(s))
1. Negative appendicectomy rate (NAR). Defined as the proportion of patients that received a negative appendicectomy measured by review of patient notes at 30 days follow up.
2. Missed or delayed appendicitis. Proportion of patients that were not correctly diagnosed with appendicitis on their first hospital attendance and review by the surgical team. The diagnosis of appendicitis must be confirmed on radiological imaging or histology. Review of patient notes at 30 days follow up.
3. Readmission or re-attendance to hospital. Discharge from the care of the general surgical team and subsequent reattendance to hospital for RIF pain. Including all patients reattending with RIF pain or post-operatively. Excludes patients with missed appendicitis. Review of patient notes at 30 days follow up.
4. Reoperation (abdominal) for any cause, measured at 30 days follow up.

5. Surgical complications, as defined by the Clavien-Dindo classification system, measured at 30 days follow up.
6. Surgical site infection, as defined by the Centers for Disease Control criteria, measured at 30 days follow up.
7. Time from symptom onset to decision to operate and to skin incision (in hours) measured during index admission.
8. Radiological, percutaneous or laparoscopic drainage measured during index admission, measured at 30 days follow up.
9. The proportion of patients with complicated appendicitis (phlegmon, abscess or perforation), measured at 30 days follow up.
10. Admission to critical care (Level 2/3 care) for any length of time, measured during index admission.
11. Mortality (both inpatient and in the community from any cause), measured at 30 days follow up using patient notes.

Completion date
16/01/2026

Eligibility

Key inclusion criteria
Patients:
1. Age 16 - 39 years
2. Attending hospital with right iliac fossa pain

Health professionals:
1. Members of the acute general surgery team

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
39 years

Sex
All

Total final enrolment
2530

Key exclusion criteria

Patients:
1. Previous appendicectomy
2. Current pregnancy
3. Patients with RIF pain under the care of secondary teams (other than general surgery team)

Heath professionals:
1. Doctors and allied health professionals that are not part of the acute general surgical team
2. Members of the general surgical team that are not involved in the diagnostic assessment and management of patients with RIF pain

Date of first enrolment
23/08/2024

Date of final enrolment
16/11/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
England
LU4 0DZ

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre

Pilgrim Hospital
Sibsey Road
Boston
England
PE21 9QS

Study participating centre
Furness Hospitals NHS Trust
Furness General Hospital
Dalton Lane
Barrow-in-furness
England
LA14 4LF

Study participating centre
Bronglais General Hospital
Bronglais Hospital
Caradoc Road
Aberystwyth
Wales
SY23 1ER

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green

Birmingham
England
B9 5ST

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Study participating centre
Warrington and Halton Teaching Hospitals NHS Foundation Trust
Warrington Hospital
Lovely Lane
Warrington
England
WA5 1QG

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Study participating centre

North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
England
CA2 7HY

Study participating centre
Dorset County Hospital NHS Foundation Trust
Dorset County Hospital
Williams Avenue
Dorchester
England
DT1 2JY

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
Scotland
G12 0XH

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
England
TA1 5DA

Study participating centre

University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
Northern Ireland
BT63 5QQ

Study participating centre
Tayside
Ninewells Hospital
Dundee
Scotland
DD1 9SY

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston

England
PE21 9QS

Study participating centre
Prince Charles Hospital Site
Prince Charles Hospital
Merthyr Tydfil
Wales
CF47 9DT

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

Study participating centre
Burton Hospital
Queens Hospital
Belvedere Road
Burton-on-trent
England
DE13 0RB

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
England
N19 5NF

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
England
CF14 4XW

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
England
CH49 5PE

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
Wye Valley NHS Trust
County Hospital
27 Union Walk
Hereford
England
HR1 2ER

Study participating centre

New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
Midland Metropolitan University Hos
Grove Lane
Smethwick
England
B66 2QT

Study participating centre
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
Dumfries and Galloway
Scotland
DG1 4AP

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
Wales
CF72 8XR

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
Scotland
FK5 4WR

Study participating centre
Tameside and Glossop Integrated Care NHS Foundation Trust
Tameside General Hospital
Fountain Street

Ashton-under-lyne
England
OL6 9RW

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
England
SY3 8XQ

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study will be stored in a non-publicly available repository (Redcap - https://bistc.redcap.bham.ac.uk/).
Our participants are doctors and clinicians with the acute surgical team. The final dataset will comprise the datasets from all eligible patients. The data stored will include details on:
- Baseline characteristics
- Investigations performed
- Clinical management
- Clinical outcomes at 30-day follow up.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	07/07/2025	16/12/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes