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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
Recruiting

Registration date
03/09/2024

Overall study status
Ongoing

Last Edited
08/10/2024

Condition category
Digestive System

[ ] 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
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 December 2025.

Who is funding the study?
Investigator initiated and funded

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

Study website
https://claritytrial.co.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334172

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG_24-022, IRAS 334172

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic, Efficacy

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures

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.

Overall study start date
29/05/2024

Completion date
30/12/2025

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)
Patient, Health professional

Age group
Adult

Lower age limit
16 Years

Upper age limit
39 Years

Sex
Both

Target number of participants
4800

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
01/12/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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

Study participating centre

Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston
United Kingdom
PE21 9QS

Study participating centre
Furness Hospitals NHS Trust
Furness General Hospital
Dalton Lane
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LA14 4LF

Study participating centre
Bronglais General Hospital
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SY23 1ER

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

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh

Lothian
United Kingdom
EH4 2XU

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
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B9 5ST

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
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Sponsor information

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal(s) and presentation at national and international conference(s).

Intention to publish date
30/12/2026

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