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Managing gallstone disease in the elderly

Submission date
17/10/2022

Recruitment status
Recruiting

Registration date
16/12/2022

Overall study status
Ongoing

Last Edited
08/03/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Patients over 70 years old are very commonly admitted to the hospital with problems caused by gallstones, such as pain, infection, jaundice and pancreatitis (inflammation of the pancreas, a digestive organ which can get blocked by gallstones). Some people have their gallbladder removed during their initial admission and others are treated first with medical therapy (such as antibiotics or endoscopy) and then brought back later to have their gallbladder removed as a planned (or “elective”) operative. This usually prevents further problems caused by gallstones. For a number of reasons, including frailty or other medical problems, surgery is not considered the appropriate treatment for some patients.
Very little is known about what happens to these patients in the longer term – such as whether the gallstones do cause more problems and how this affects their quality of life. This study aims to follow up with patients who were admitted to the hospital with gallstone disease to assess how this has affected them for up to three years after their initial diagnosis and compare those who did and those who did not have surgery. Patients will be contacted regularly to ask whether they have any ongoing symptoms and how this affects their quality of life. This is an observational study which will not affect which treatment each patient receives – this will be decided as normal by the team treating them in the hospital. A better understanding of what happens to patients after surgical and non-surgical treatment would allow doctors to have more informed discussions with patients about the likely outcomes of each treatment and improve their ability to make a joint decision about whether surgery is the best option.

Who can participate?
Patients aged 70 years old and over who have been admitted to the hospital in an emergency with gallbladder problems

What does the study involve?
The treatment will be exactly the same whether a patient takes part or not. Information will be collected about the patient while they are in the hospital from their medical records and then they will be contacted by telephone 30 days, 1 year and 3 years after their admission to ask them some questions about how they are feeling, whether they have been admitted to hospital again with gallstones and about their quality of life. The research team may also contact their GP or access your medical notes at these time points in order to record details about their health relevant to the trial.

What are the possible benefits and risks of participating?
There are no direct benefits to you from taking part but we hope this will help us improve the way we treat older patients with gallstones in the future. There will be no disadvantage to you from taking part, as you will receive the same standard treatment regardless. The three follow up telephone calls should only take approximately 15 minutes each and you will not need to attend any appointments as part of the trial. There are no additional risks to you in this study.

Where is the study run from?
Wessex Research Collective (UK) and is sponsored by Portsmouth Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)
Rosetrees Trust (UK)

Who is the main contact?
Ms Amy Lord (UK)
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Contact information

Type(s)
Public

Contact name
Ms Amy Lord

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Study Lead/Co-Ordinator (off-site)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
301556

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52135, IRAS 301556

Study information

Scientific Title
Managing gallstone disease in the elderly: comparing quality of life and outcomes after operative and non-operative treatment

Acronym
MANGO

Study objectives

Re-admission rate for patients with symptomatic gallstone disease managed non-operatively will be higher than those who have a cholecystectomy

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/06/2022, HRA and Health and Care Research Wales (HCRW) (Address: not available; Tel: not available; approvals@hra.nhs.uk, HCRW.approvals@wales.nhs.uk), ref: 22/NS/0026
2. Approved 01/03/2022, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK ; +44(0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0026

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Upper gastrointestinal surgery

Interventions
Patients will be recruited to the study when they are admitted to the hospital with gallstone disease. The study will be explained to them and they will be asked to complete a consent form if they wish to take part. In patients who consent, data will be extracted from their medical records about their diagnosis, any operations and treatments they receive and the events during admission, such as complications. Patients will undergo standard treatment as determined by their medical team and no changes will be made as a result of participating in the study.

Patients will be followed up by telephone 30 days, 1 year and 3 years after their initial admission to assess whether they have had further problems or complications and what their quality of life is like (using a standardised and validated questionnaire). Hospital records will also be re-assessed at these time points to gain information about any subsequent admissions, operations, etc.

The group of patients who have surgery will be compared to those who do not.
We will compare:
1. The number of patients who require readmission to the hospital due to gallstone disease for

each group
2. The number of complications for each group of patients
3. The number of patients who die in each group
4. The quality of life for each group

Intervention Type
Other

Primary outcome measure
To compare gallstone-related readmission rates among operative and non-operative groups (count [%]) measured by interrogating patient medical records at 30 days, 1 year and 3 years

Secondary outcome measures
1. Morbidity: the number of patients who have complications (count [%) measured by interrogating patient medical records at the end of the study
2. Mortality: the number of patients who passed away (count [%]) measured by interrogating patient medical records at 30 days, 1 year and 3 years.
3. Quality of life measured using the Gastrointestinal Quality of Life Index (GIQLI) questionnaire at 30 days, 1 year and 3 years.

Overall study start date
01/09/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 70 years old and over
2. Admitted acutely to the hospital with a disorder caused by gallstones (i.e. biliary colic, cholecystitis, gallstone pancreatitis, choledocholithiasis or cholangitis)
3. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
70 Years

Sex
Both

Target number of participants
Planned Sample Size: 260; UK Sample Size: 260

Key exclusion criteria

1. Aged 69 years old and under
2. Unwilling or unable to give informed consent

Date of first enrolment
21/10/2022

Date of final enrolment
10/10/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Isle of Wight NHS Trust Nmp
St Mary's Hospital
Parkhurst Road
Newport

United Kingdom
PO30 5TG

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
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United Kingdom
SP2 8BJ

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Dorset County Hospital Laboratory
Dorset County Hospital
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Dorchester
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DT1 2JY

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Central Commissioning Facility (CCF)

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
Rosetrees Trust

Alternative Name(s)
Teresa Rosenbaum Golden Charitable Trust, Rosetrees

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Conference presentation
3. Publication on a website

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The study datasets will be stored on secure servers in the Research Department at PHU and accessible to the relevant members of the research team.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	21/03/2022	19/10/2022	No	Yes
HRA research summary			28/06/2023	No	No
Protocol file	version 1.3	12/10/2022	08/03/2024	No	No