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Exercise in mesothelioma study

Submission date
02/08/2024

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Completed

Last Edited
06/11/2024

Condition category
Cancer

[ ] 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
Malignant pleural mesothelioma (MPM) is an aggressive cancer that is strongly associated with asbestos exposure. It most frequently affects the lining of the lung (pleura), but can also affect the other parts of the body, including the lining of the heart and abdomen. Patients with MPM often experience troublesome symptoms including breathlessness, pain and fatigue. They can also experience anxiety and depression and feel like their quality of life is worse than before they were diagnosed. Unfortunately, the average life expectancy following a diagnosis of mesothelioma is about 12 months. Currently, treatment in patients who are fit enough is aimed at prolonging this life expectancy and involves drug treatment in the form of either chemotherapy or more recently immunotherapy. Whether a person with mesothelioma receives this treatment can depend on their physical fitness. Improving health-related quality of life (HRQoL) and physical fitness is a key goal for all patients with MPM, and maximising treatment opportunities has never been more important following the recent approval of immunotherapy for the treatment of MPM across the UK. Exercise therapy is a rational approach to improving HRQoL and could also improve and/or maintain physical fitness to allow more patients to ultimately receive treatment. There is currently no evidence for the role of exercise therapy in mesothelioma. The aim of this study is to determine whether it is feasible to recruit and randomise patients with mesothelioma in a study of exercise therapy.

Who can participate?
Patients aged 18 years and over with mesothelioma

What does the study involve?
Once a participant consents to the study, they will undergo a baseline assessment, which will include the completion of an HRQoL questionnaire and a fitness assessment, which will include a 6-minute walk test (which measures the distance the participant can walk in 6 minutes), a hand grip strength measurement and counting how many times the participant can rise from a chair in 30 seconds (30-second sit to stand test). Once this baseline assessment has been completed, participants are randomly allocated to either intervention or standard of care. The intervention group involves the participant being assessed by a qualified physiotherapist or qualified exercise specialist with specialist cancer training before being provided with a 12-week personalised exercise and wellbeing programme, which includes exercise three times per week. Participants will be asked to complete HRQoL questionnaires at about 8, 16 and 26 weeks after enrolment; and functional fitness testing at 16 weeks after enrolment. The standard of care group involves

routine clinical follow-up with completion of HRQoL questionnaires at about 8, 16 and 26 weeks after enrolment; and functional fitness testing at 16 weeks after enrolment.

What are the possible benefits and risks of participating?
It is possible that a personalised exercise programme could improve symptoms and quality of life in patients with mesothelioma. However, it is important to stress that this is not yet proven and will need testing in a larger study if the current study shows promising results.
Exercise in patients with mesothelioma is generally safe, however, exercise can be associated with complications such as joint pain, muscle soreness, injury and fatigue. Very uncommonly, exercise can be associated with heart attack or heart rhythm abnormality, but this is rare, even in people with a heart condition and extremely rare in people who do not have pre-existing heart conditions.

Where is the study run from?
The study is run from two UK mesothelioma centres: The Queen Elizabeth University Hospital in Glasgow and Wythenshawe Hospital in Manchester.

When is the study starting and how long is it expected to run for?
July 2023 to July 2025

Who is funding the study?
Mesothelioma UK

Who is the main contact?
Dr Selina Tsim, selina.tsim@glasgow.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Selina Tsim

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
315059

ClinicalTrials.gov number
NCT06491784

Secondary identifying numbers
CPMS 58172

Study information

Scientific Title
EXercise TheRApy in Mesothelioma - The EXTRA-Meso feasibility study

Acronym
EXTRA-Meso

Study objectives
Study hypothesis is that it is feasible to recruit patients with mesothelioma to a randomised study of exercise therapy versus standard care

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/10/2023, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 23/WM/0186

Study design
Multi-centre non-blinded randomized feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other, Quality of life, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mesothelioma

Interventions

Once a participant consents to the study, they will undergo a baseline assessment, which will include the completion of an HRQoL questionnaire and a fitness assessment, which will include a 6-minute walk test (which measures the distance the participant can walk in 6 minutes), a hand grip strength measurement and counting how many times the participant can rise from a chair in 30 seconds (30-second sit to stand test). Once this baseline assessment has been completed, participants are randomly allocated to either intervention or standard of care. Randomisation is a 1:1 randomisation using random permuted blocks via a validated online system (sealedenvelope.com). The intervention group involves the participant being assessed by a qualified physiotherapist or qualified exercise specialist with specialist cancer training before being provided with a 12-week personalised exercise and wellbeing programme, which includes exercise three times per week. Participants will be asked to complete HRQoL questionnaires at about 8, 16 and 26 weeks after enrolment; and functional fitness testing at 16 weeks after enrolment. The standard of care group involves routine clinical follow-up with completion of HRQoL questionnaires at about 8, 16 and 26 weeks after enrolment; and functional fitness testing at 16 weeks after enrolment.

Intervention Type
Other

Primary outcome measure
Total number of patients recruited over 12 months

Secondary outcome measures
1. Proportion of screened patients who do not meet study eligibility over 12 months
2. Of the patients who fail screening, which eligibility criteria have they failed to meet, over the 12-month recruitment period
3. Study drop-out rate, described as the proportion of patients enrolled in the study who withdraw before the end of the study period
4. Reasons for study drop-out (free text) recorded over the duration of the study period (18 months)
5. Intervention adherence rate, described as the proportion of patients randomised to exercise therapy who complete the 12-week exercise programme
6. Adverse events recorded over the duration of the study period (18 months)
7. Health-related quality of life (HRQoL) questionnaire completion rate, described as the proportion of questionnaires completed by study participants over the duration of the study period (18 months)

Overall study start date
01/07/2023

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Diagnosis of mesothelioma, ratified by a mesothelioma multi-disciplinary team (MDT)
2. Performance status 0 - 2
3. Clinical frailty score ≤5
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Performance status ≥3
2. Clinical frailty score ≥6
3. Unlikely to be able to participate in an exercise programme (clinician/physiotherapist judgement)

Date of first enrolment
30/01/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
Research & Innovation
Dykebar Hospital
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Paisley
Glasgow
Scotland
United Kingdom
PA2 7DE
+44 (0)141 314 4001
Kirsty.Theron@ggc.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Mesothelioma UK

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Selina Tsim (selina.tsim@glasgow.ac.uk).

Data (HRQOL summary, functional fitness data summary, intervention adherence and dropout rate) will become available at the completion of study follow-up and data cleaning (approximately 31/10/2025). Consent to do so will be sought from participants via the participant information sheet and study consent form. All data would be anonymised as per ethical approval.

IPD sharing plan summary
Available on request