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A study to test whether adding nivolumab to TACE/TAE treatment is effective and safe in patients with intermediate-stage liver cancer

Submission date 10/01/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/01/2019	**Overall study status** Ongoing	
Last Edited 08/04/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-nivolumab-and-chemoembolisation-for-cancer-of-the-liver-tace-3

Contact information

Type(s)
Scientific

Contact name
Dr Brenda Hall

Contact details
Liverpool Clinical Trials Centre
The University of Liverpool
Block C, Waterhouse Building
1-5 Brownlow Street
Liverpool
United Kingdom
L69 3GL
+44 (0)151 795 1555
tace3@liverpool.ac.uk

Type(s)
Scientific

Contact name
Dr Charlotte Rawcliffe

Contact details

LCTC Head of Trials Management
Liverpool Clinical Trials Centre
The University of Liverpool
Block C, Waterhouse Building
1-5 Brownlow Street
Liverpool
United Kingdom
L69 3GL
+44 (0)151 794 8167
c.rawcliffe@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
2018-000004-42

IRAS number

ClinicalTrials.gov number
NCT04268888

Secondary identifying numbers
C0993

Study information

Scientific Title
A two-arm multi-stage (TAMS) seamless phase II/III randomised trial of nivolumab in combination with TACE/TAE for patients with intermediate stage HCC

Acronym
TACE-3

Study objectives
Current study hypothesis as of 15/07/2020:
The primary purpose of Phase II component of the study is to evaluate efficacy of nivolumab in combination with TACE/TAE in patients with intermediate stage HCC and to recommend continuation into Phase III component if a positive efficacy signal is observed using TACE/TAE progression (TTTP) at 3 months as primary outcome measure.

The primary purpose of the Phase III component of the study is to evaluate the difference in overall survival between nivolumab in combination with TACE/TAE in patients with intermediate stage HCC.

The null hypothesis is that the addition of Nivolumab to TACE/TAE has no effect on overall survival.

Previous study hypothesis:
The primary purpose of Phase II component of the study is to evaluate efficacy of nivolumab in combination with TACE in patients with intermediate stage HCC and to recommend continuation

into Phase III component if a positive efficacy signal is observed using TACE progression (TTTP) at 3 months as primary outcome measure.

The primary purpose of the Phase III component of the study is to evaluate the difference in overall survival between nivolumab in combination with TACE in patients with intermediate stage HCC.

The null hypothesis is that the addition of Nivolumab to TACE has no effect on overall survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/01/2019, RES Committee North West – GM South (Health Research Authority, 3rd Floor, Barlow House, 4 Minshull St., Manchester, M1 3DZ, Tel: +44 (0)207 104 8235, nrescommittee.northwest-gmsouth@nhs.net), ref: 18/NW/0699

Study design
Interventional multi-centre two-arm open-label seamless phase II/III study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Intermediate stage hepatoceullular carcinoma

Interventions
Current interventions as of 15/07/2020:
Patients are randomised 1:1 between two treatment arms:
1. TACE/TAE treatment (standard treatment)
2. Nivolumab (480mg IV - 4 weekly) and TACE/TAE treatment (experimental arm)

Patients will undergo screening assessments to determine whether they are eligible for inclusion in the study, which may include a liver biopsy. They will also complete some questionnaires.

The length of treatment is partly determined by how well patients respond to treatment. Based on assessment data, the doctor may recommend repeat TACE/TAE treatment, with each treatment taking around 1-2 hours to complete with an overnight stay in hospital.

Patients who also receive nivolumab treatment will attend for regular 4 weekly treatment visits until the doctor decides no further nivolumab treatment is necessary or when the maximum treatment period is reached (24 months).

After treatment has ended, patients are followed-up every 4 weeks for a minimum of 24 months if possible (maximum is end of study).

Patients will have CT ±MRI scans throughout the study (prior to treatment, 4 weeks after the first TACE/TAE and then 12 weekly). If disease progression occurs, a confirmatory CT ±MRI scan will be performed.

In addition to routine blood samples, patients will be asked to provide blood samples throughout the study for future liver cancer research.

Most patients will be identified by the Investigator/Co-Investigator responsible for their care. Some may be identified by colleagues who know about the trial but are not directly involved in the study. In such instances the patients' doctors will refer them to the study doctor.

Patients may also be identified at multi-disciplinary team meetings at their hospital. These meetings are held to discuss the patients' care, and are attended by the clinical care team (consultants, radiologists, research nurses, etc.). Identification is based upon the inclusion /exclusion criteria.

If the patient appears eligible the study doctor will inform the patient of the study and the trial will be discussed during the patient consultation. All patients will be given adequate time to ask questions about the trial before being asked to participate. If the patient agrees to take part the informed consent process will begin.

Patients shall be randomised evenly across the two treatment arms of the study. In phase II of the study, 100 patients will be recruited.

A stop/go decision in the phase II component of the study is based on observing some evidence of effectiveness between the treatment arms with respect to 3-month TACE/TAE progression. This will occur after 100 patients have had a 20 week scan for TACE/TAE progression, which will occur approximately 18 months following the start of recruitment.

Aside from the stop/go decision, there are no formal stopping rules for efficacy/futility built into the study.

Should the study continue to phase III, 422 patients will be randomised evenly across the two treatment arms. This makes a total of 522 patients being recruited over a 48 month period for phase II and III combined, with a minimum 24 months of follow-up for each patient if possible.

Patient recruitment is planned to take place from 16 contributing centres who (based on estimations from the TACE 2 study) will conservatively be able to recruit at an average rate of 0.75 patients/site/month. Sites will be opened to recruitment at a rate of 2 sites per month. These projections include a 5% shortfall margin (attrition rate).

A Trial Management Group (comprising the Chief Investigator, other lead investigators [clinical and non-clinical] and members of the Liverpool Clinical Trials Centre) will manage the day to day running of the study and will meet throughout the study.

The Independent Safety and Data Monitoring Committee (ISDMC) (consisting of an independent chairperson, independent statistician and an independent oncologist who are experts in the field of oncology and liver cancer) are responsible for reviewing and assessing recruitment, interim monitoring of safety and effectiveness, trial conduct and external data and will provide a recommendation to the Trial Steering Committee concerning the continuation of the study.

The Trial Steering Committee (consisting of an independent chairperson, independent statistician and independent experts in the field of liver cancer in addition to other non-independent members of the TMG) provides overall supervision and advice for the study. The ultimate decision for the continuation of the trial lies with the TSC.

The patient information sheet and consent forms have been reviewed by members of the University of Liverpool, Liverpool Clinical Trials Centre, Patient and Public Involvement group, which consists of lay members of the public. The forms have subsequently been re-designed to include suggestions made by the PPI group, with the overall goal being to improve the effectiveness of the forms in communicating the requirements and expectations of the study to patients.

The Trial Steering Committee also includes lay member representation.

Previous interventions:
Patients are randomised 1:1 between two treatment arms:
1. TACE treatment (standard treatment - DC Beads loaded with doxorubicin)
2. Nivolumab (480mg IV - 4 weekly) and TACE treatment (experimental arm)

Patients will undergo screening assessments to determine whether they are eligible for inclusion in the study, which may include a liver biopsy. They will also complete some questionnaires.

The length of treatment is partly determined by how well patients respond to treatment. Based on assessment data, the doctor may recommend repeat TACE treatment, with each treatment taking around 1-2 hours to complete with an overnight stay in hospital.

Patients who also receive nivolumab treatment will attend for regular 4 weekly treatment visits until the doctor decides no further nivolumab treatment is necessary or when the maximum treatment period is reached (24 months).

After treatment has ended, patients are followed-up every 4 weeks for a minimum of 24 months if possible (maximum is end of study).

Patients will have CT/MRI scans throughout the study (prior to treatment, 8 weeks after they have entered the study and then 12 weekly). If disease progression occurs, a confirmatory CT /MRI scan will be performed.

In addition to routine blood samples, patients will be asked to provide blood samples throughout the study for future liver cancer research.

Most patients will be identified by the Investigator/Co-Investigator responsible for their care. Some may be identified by colleagues who know about the trial but are not directly involved in the study. In such instances the patients' doctors will refer them to the study doctor.

Patients may also be identified at multi-disciplinary team meetings at their hospital. These meetings are held to discuss the patients' care, and are attended by the clinical care team (consultants, radiologists, research nurses, etc.). Identification is based upon the inclusion /exclusion criteria.

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A Trial Management Group (comprising the Chief Investigator, other lead investigators [clinical and non-clinical] and members of the LCTU Trials Unit) will manage the day to day running of the study and will meet throughout the study.

The Independent Safety and Data Monitoring Committee (ISDMC) (consisting of an independent chairperson, independent statistician and an independent oncologist who are experts in the field of oncology and liver cancer) are responsible for reviewing and assessing recruitment, interim monitoring of safety and effectiveness, trial conduct and external data and will provide a recommendation to the Trial Steering Committee concerning the continuation of the study.

The Trial Steering Committee (consisting of an independent chairperson, independent statistician and independent experts in the field of liver cancer in addition to other non-independent members of the TMG) provides overall supervision and advice for the study. The ultimate decision for the continuation of the trial lies with the TSC.

The patient information sheet and consent forms have been reviewed by members of the University of Liverpool, CR-UK Liverpool Cancer Trials Unit Patient and Public Involvement group, which consists of lay members of the public. The forms have subsequently been re-

designed to include suggestions made by the PPI group, with the overall goal being to improve the effectiveness of the forms in communicating the requirements and expectations of the study to patients.

The Trial Steering Committee also includes lay member representation.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Nivolumab

Primary outcome measure
Current primary outcome measures as of 15/07/2020:
Phase II:
3 month TACE/TAE Progression (TTTP) (binary), assessed using CT ±MRI scan at 3 months

Phase III:
Overall survival, assessed using hospital records from randomisation to death

Previous primary outcome measures:
Phase II:
3 month TACE Progression (TTTP) (binary), assessed using CT/MRI scan at 3 months

Phase III:
Overall survival, assessed using hospital records from randomisation to death

Secondary outcome measures
Current secondary outcome measures as of 15/07/2020:
Phase II:
1. Number of Grade 3+ AEs and SAEs, assessed by asking patient at baseline, each treatment visit, and 4 weekly during follow-up
2. Progression Free Survival (PFS), assessed using CT ±MRI scan from randomisation to progression or death
3. Time to progression (TTP), assessed using CT ±MRI scan from randomisation to progression
4. Response rate by RECIST 1.1, assessed using CT ±MRI scan at 4 weeks post the first TACE/TAE and then 12 weekly

Phase III:
1. Time to TACE/TAE Progression (TTTP), assessed using CT ±MRI scan at 8 weeks post randomisation and confirmatory scan 4 weeks after progression
2. Number of Grade 3+ AEs and SAEs, assessed by asking patient at baseline, each treatment visit, 4 weekly during follow-up
3. Progression Free Survival (PFS), assessed using CT ±MRI scan, hospital records, from randomisation to progression or death
4. Time to progression (TTP), assessed using CT ±MRI scan from randomisation to progression
5. Objective response rate (ORR) by RECIST 1.1, assessed using CT ±MRI scan at 8 weeks post randomisation and then 12 weekly

6. Quality of life, assessed using EORTC QLQ_C30, EORTC QLQ-HCC18 and EQ5D questionnaires at baseline, pre-first TACE/TAE treatment and then 12 weekly until end of treatment

Previous secondary outcome measures:
Phase II:
1. Number of Grade 3+ AEs and SAEs, assessed by asking patient at baseline, each treatment visit, and 4 weekly during follow-up
2. Progression Free Survival (PFS), assessed using CT/MRI scan from randomisation to progression or death
3. Time to progression (TTP), assessed using CT/MRI scan from randomisation to progression
4. Response rate by RECIST 1.1, assessed using CT/MRI scan at 8 weeks post randomisation and then 12 weekly

Phase III:
1. Time to TACE Progression (TTTP), assessed using CT/MRI scan at 8 weeks post randomisation and confirmatory scan 4 weeks after progression
2. Number of Grade 3+ AEs and SAEs, assessed by asking patient at baseline, each treatment visit, 4 weekly during follow-up
3. Progression Free Survival (PFS), assessed using CT/MRI scan, hospital records, from randomisation to progression or death
4. Time to progression (TTP), assessed using CT/MRI scan from randomisation to progression
5. Objective response rate (ORR) by RECIST 1.1, assessed using CT/MRI scan at 8 weeks post randomisation and then 12 weekly
6. Quality of life, assessed using EORTC QLQ_C30, EORTC QLQ-HCC18 and EQ5D questionnaires at baseline, pre-first TACE treatment and then 12 weekly until end of treatment

Overall study start date
31/08/2017

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/07/2020:
1. Histological diagnosis* of HCC and at least one uni-dimensional lesion measurable according to RECIST 1.1 criteria by CT-scan ± MRI
2. Not a candidate for surgical resection or liver transplantation**
3. Aged ≥16 years and estimated life expectancy >3 months
4. ECOG performance status 0-1
5. Adequate haematological function:
5.1. Hb ≥9g/L
5.2. Absolute neutrophil count ≥1.0x109/L
5.3. Platelet count ≥60x109/L
6. Bilirubin ≤50 µmol/L, AST, ALT and ALP ≤5 x ULN
7. Adequate renal function; Creatinine µmol/L ≤ 1.5 x ULN
8. INR ≤1.6
9. Child-Pugh A (score ≤6) (Appendix D)
10. HAP score A, B or C (Appendix E)
11. No contra-indications to T-cell checkpoint inhibitor therapy (use of immunosuppressive drugs

including steroids at dose equivalent to prednisolone >10mg/day unless used as replacement therapy; organ transplantation; subjects with an active, known or suspected autoimmune disease. Subjects with type I diabetes mellitus, hypothyroidism only requiring hormone replacement, skin disorders (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment, lichen planus or other conditions not expected to recur in the absence of an external trigger are permitted to enrol).
12. Women of child-bearing potential should have a negative pregnancy test prior to study entry. Both men and women must be using an adequate contraception method, which must be continued for 5 months after completion of treatment for women and 7 months for men
13. Written informed consent

*All patients are required to under a MANDATORY biopsy prior to entry onto the study
**Criteria which establish 'intermediate' HCC

Previous inclusion criteria:
1. Histological diagnosis* of HCC and at least one uni-dimensional lesion measurable according to RECIST 1.1 criteria by CT-scan or MRI
2. Not a candidate for surgical resection or liver transplantation**
3. Aged ≥16 years and estimated life expectancy >3 months
4. ECOG performance status 0-1
5. Adequate haematological function:
5.1. Hb ≥9g/L
5.2. Absolute neutrophil count ≥1.0x109/L
5.3. Platelet count ≥60x109/L
6. Bilirubin ≤50 µmol/L, AST,ALT and ALP ≤5 x ULN
7. Adequate renal function; Creatinine ≤ 1.5ULN (Using Cockcroft-Gault Formula)
8. INR ≤1.7
9. Child-Pugh A (score ≤6) (Appendix D)
10. HAP score A, B or C (Appendix E)
11. No contra-indications to T-cell checkpoint inhibitor therapy (use of immunosuppressive drugs including steroids at dose equivalent to prednisolone >10mg/day unless used as replacement therapy; organ transplantation; subjects with an active, known or suspected autoimmune disease. Subjects with type I diabetes mellitus, hypothyroidism only requiring hormone replacement, skin disorders (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment, lichen planus or other conditions not expected to recur in the absence of an external trigger are permitted to enrol).
12. Women of child-bearing potential should have a negative pregnancy test prior to study entry. Both men and women must be using an adequate contraception method, which must be continued for 5 months after completion of treatment for women and 7 months for men
13. Written informed consent

*All patients are required to under a MANDATORY biopsy prior to entry onto the study
**Criteria which establish 'intermediate' HCC

Participant type(s)
Patient

Age group
Adult

Lower age limit

16 Years

Sex
Both

Target number of participants
Planned Sample Size: 522; UK Sample Size: 422

Key exclusion criteria
1. Extrahepatic metastasis*
2. Prior embolisation, systemic or radiation therapy for HCC*
3. Any contraindications for hepatic embolisation procedures including portosystemic shunt, hepatofugal blood flow, known severe atheromatosis
4. Investigational therapy or major surgery within 4 weeks of trial entry
5. History of variceal bleeding within the past 4 weeks
6. Child-Pugh cirrhosis B or C (score > = 7)
7. HAP score D
8. Hepatic encephalopathy
9. Ascites refractory to diuretic therapy
10. Documented occlusion of the hepatic artery or main portal vein5
11. Hypersensitivity to intravenous contrast agents
12. Active clinically serious infection > Grade 2 NCI-CTC
13. Pregnant or lactating women
14. Known history of HIV infection
15. HBV chronic infection with HBV DNA ≥ 500IU/mL or without antiviral therapy; HBV patients with cirrhosis should be treated.
16. History of serious autoimmune disease.
17. History of second malignancy except those treated with curative intent more than three years previously without relapse and non-melanotic skin cancer or cervical carcinoma in situ
18. Evidence of severe or uncontrolled systemic disease, or laboratory finding that in the view of the Investigator makes it undesirable for the patient to participate in the trial
19. Psychiatric or other disorder likely to impact on informed consent
20. Patient is unable and/or unwilling to comply with treatment and study instructions

*Criteria which establish ‘intermediate’ HCC

Date of first enrolment
01/02/2019

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
England

France

Scotland

United Kingdom

Study participating centre
THE CLATTERBRIDGE CANCER CENTRE NHS FOUNDATION TRUST
CLATTERBRIDGE ROAD
BEBINGTON WIRRAL
United Kingdom
CH63 4JY

Study participating centre
ROYAL LIVERPOOL AND BROADGREEN UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
PRESCOT STREET
LIVERPOOL
United Kingdom
L7 8XP

Study participating centre
AINTREE UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
LOWER LANE
LIVERPOOL
United Kingdom
L9 7AL

Study participating centre
KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
DENMARK HILL
LONDON
United Kingdom
SE5 9RS

Study participating centre
UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
TRUST HQ, PO BOX 9551
QUEEN ELIZABETH MEDICAL CENTRE
EDGBASTON
BIRMINGHAM
United Kingdom
B15 2TH

Study participating centre
NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
TRUST HEADQUARTERS
QUEENS MEDICAL CENTRE
DERBY ROAD
NOTTINGHAM
United Kingdom
NG7 2UH

Study participating centre
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
MAILPOINT 18
SOUTHAMPTON GENERAL HOSPITAL
TREMONA ROAD
SOUTHAMPTON
United Kingdom
SO16 6YD

Study participating centre
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST
MARLBOROUGH STREET
BRISTOL
United Kingdom
BS1 3NU

Study participating centre
THE CHRISTIE NHS FOUNDATION TRUST
550 WILMSLOW ROAD
WITHINGTON
MANCHESTER
United Kingdom
M20 4BX

Study participating centre
THE ROYAL MARSDEN NHS FOUNDATION TRUST
FULHAM ROAD
LONDON
United Kingdom
SW3 6JJ

Study participating centre

CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
ADDENBROOKES HOSPITAL
HILLS ROAD
CAMBRIDGE
United Kingdom
CB2 0QQ

Study participating centre
ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST
EGERTON ROAD
GUILDFORD
SURREY
United Kingdom
GU2 7XX

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

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

Study participating centre
HEART OF ENGLAND NHS FOUNDATION TRUST
BORDESLEY GREEN EAST
BIRMINGHAM
United Kingdom
B9 5ST

Study participating centre

THE ROYAL BOURNEMOUTH AND CHRISTCHURCH HOSPITALS NHS FOUNDATION TRUST
CASTLE LANE EAST
BOURNEMOUTH
United Kingdom
BH7 7DW

Study participating centre
OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
JOHN RADCLIFFE HOSPITAL
HEADLEY WAY
HEADINGTON
OXFORD
United Kingdom
OX3 9DU

Study participating centre
ROYAL FREE LONDON NHS FOUNDATION TRUST
ROYAL FREE HOSPITAL
POND STREET
LONDON
United Kingdom
NW3 2QG

Study participating centre
MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
COBBETT HOUSE
OXFORD ROAD
MANCHESTER
United Kingdom
M13 9WL

Study participating centre
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
FREEMAN HOSPITAL
FREEMAN ROAD
HIGH HEATON
NEWCASTLE-UPON-TYNE
United Kingdom
NE7 7DN

Study participating centre

Gustave Roussy
114 Rue Edouard Vaillant
Villejuif
France
94800 Villejuif

Study participating centre
CHU, Centre Hospitalier Universitaire de Montpellier
191 avenue du Doyen Gaston Giraud
Montpellier
France
34295 Montpellier cedex 5

Study participating centre
CHU, 2 Rue de la Milétrie
CHU, 2 Rue de la Milétrie
Poitiers
France
86021 Poitiers

Study participating centre
Hôpital Beaujon
100 Boulevard du Général Leclerc
Clichy
France
92110 Clichy

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

Study participating centre
Centre Eugene Marquis
Rue de la Bataille Flandres Dunkerque

Rennes
France
35042

Sponsor information

Organisation
The Clatterbridge Cancer Centre NHS Foundation Trust

Sponsor details
Clatterbridge Road
Bebington
England
United Kingdom
CH63 4JY

Sponsor type
Hospital/treatment centre

Website
https://www.clatterbridgecc.nhs.uk/

ROR
https://ror.org/05gcq4j10

Funder(s)

Funder type
Industry

Funder Name
Bristol-Myers Squibb

Alternative Name(s)
Bristol-Myers Squibb Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
All study documents will be available by contacting the Trial Coordinator only.

The study will accessible on the following registers:
1. ISRCTN registry
2. eudract.ema.europa.eu

The results will be reported and disseminated via:
1. Peer-reviewed scientific journals
2. Internal reports
3. Conference presentations
4. Submission to regulatory authorities

Results of the research will be made available to all of the participating investigators, who will then communicate the results to the research participants and their families. The results will also be presented at international meetings/conference proceedings which will be accessible to patients.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The database name is MACRO. The study will collect patient data from participating study centres about patients who have consented to the study. The trialists will collect anonymised patient CRF study data and unblinded consent forms to demonstrate the patient has consented to the study (consent details will never be released). This data will be held at the University of Liverpool for 15 years where it will be analysed by members of the Trial Management Group for the purposes of informing the study oversight committees during the study in addition to producing study publications.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No