

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

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
10/01/2019	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
16/01/2019	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/04/2024	Cancer	<input type="checkbox"/> Record updated in last year

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>

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Additional identifiers

Clinical Trials Information System (CTIS)
2018-000004-42

ClinicalTrials.gov (NCT)
NCT04268888

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intermediate stage hepatocellular 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.

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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(s)

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

Key secondary outcome(s)

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

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 ≥ 9 g/L
 - 5.2. Absolute neutrophil count $\geq 1.0 \times 10^9/L$
 - 5.3. Platelet count $\geq 60 \times 10^9/L$
6. Bilirubin $\leq 50 \mu\text{mol}/L$, AST, ALT and ALP $\leq 5 \times \text{ULN}$
7. Adequate renal function; Creatinine $\mu\text{mol}/L \leq 1.5 \times \text{ULN}$
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 $>10\text{mg}/\text{day}$ 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 undergo 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 $\geq 9\text{g/L}$
 - 5.2. Absolute neutrophil count $\geq 1.0 \times 10^9/\text{L}$
 - 5.3. Platelet count $\geq 60 \times 10^9/\text{L}$
6. Bilirubin $\leq 50 \mu\text{mol/L}$, AST, ALT and ALP $\leq 5 \times \text{ULN}$
7. Adequate renal function; Creatinine $\leq 1.5 \text{ULN}$ (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 $>10\text{mg/day}$ 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 undergo a MANDATORY biopsy prior to entry onto the study

**Criteria which establish 'intermediate' HCC

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

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 vein

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 \geq 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

United Kingdom

England

Scotland

France

Study participating centre

THE CLATTERBRIDGE CANCER CENTRE NHS FOUNDATION TRUST

CLATTERBRIDGE ROAD

BEBINGTON WIRRAL

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Study participating centre

ROYAL LIVERPOOL AND BROADGREEN UNIVERSITY HOSPITALS NHS FOUNDATION TRUST

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CHU, 2 Rue de la Milétrie

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Study participating centre

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Rennes
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Sponsor information

Organisation

The Clatterbridge Cancer Centre NHS Foundation Trust

ROR

<https://ror.org/05gcq4j10>

Funder(s)

Funder type

Industry

Funder Name

Bristol-Myers Squibb

Alternative Name(s)

Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers Company, BMS

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes