

Renal Adjuvant Multiple Arm Randomised Trial (RAMPART)

Submission date 22/09/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/10/2017	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/09/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <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-looking-at-durvalumab-and-tremelimumab-for-kidney-cancer-rampart#undefined> (added 13/08/2020)

Background and study aims

Renal cell carcinoma is a type of kidney cancer that starts from the kidneys. It is the 8th most common cancer in the UK and an increase of new cases of 2% has been seen in the last 20 years. About half of the new cases of kidney cancer are among people aged 70 and over. Patients whose disease has not spread outside the kidneys typically have surgery to remove a part or all of their kidney (called a partial or radical nephrectomy). After surgery, patients are seen by their doctor with regular check-ups to look for signs of the cancer coming back or spreading to other parts of the body. This is generally called 'active monitoring' or 'active surveillance'.

Unfortunately, it is estimated that the cancer will return in 30-40% of the patients who have undergone surgery. Many studies have been carried out to find if a new treatment after surgery might slow the cancer coming back or prevent it from coming back altogether. However, to date no treatment is available. Immunotherapy is a type of cancer treatment that 'wakes up' the patient's own immune system so it can fight the cancer. New drugs which act in this way have worked well in patients with skin cancer (melanoma), lung cancer and in patients with kidney cancer that has spread outside the kidney. This study is looking at two new immunotherapy treatments. The aim is to find out whether taking one drug (durvalumab) or a combination of two drugs (durvalumab and tremelimumab) for one year can prevent or delay kidney cancer from coming back compared to the current standard of care (active monitoring after surgery). Durvalumab is currently being tested (alone or in combination with other drugs) in many types of cancer. Tremelimumab is also being tested in different types of cancer.

Who can participate?

Patients aged 18 and over with renal cell carcinoma

What does the study involve?

Participants are randomly allocated to one of three groups. Group A is actively monitored for 1 year after nephrectomy. Group B is treated with durvalumab (1500 mg) administered 4 weekly for 1 year (13 cycles maximum) by intravenous infusion (into a vein). Group C is treated with durvalumab administered as per group B (13 cycles maximum) and tremelimumab on day 1 and

week 4 visits (2 cycles) by intravenous infusion. The treatment duration is 1 year maximum. Once treatment is completed, participants are seen at week 52, then 3 monthly up to the end of year 3, 6-monthly up to year 5 and annually thereafter.

What are the possible benefits and risks of participating?

If positive, the results of the study will change the current standard of care for the treatment of kidney cancer after surgery. Like all drugs, these treatments have side effects and participants have regular blood tests and scans and appointments with their study doctor and nurse.

Where is the study run from?

Participating centres are being confirmed, list of centres to be updated in due course (Australia, France, UK and USA)

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

December 2017 to December 2037

Who is funding the study?

1. Kidney Cancer UK
2. AstraZeneca (UK)
3. Medical Research Council (UK)

Who is the main contact?

1. Mr Ben Smith
mrcctu.rampart@ucl.ac.uk
2. Ms Hanna Bryant (updated 17/07/2020, previously: Dr Francesca Schiavone)
mrcctu.rampart@ucl.ac.uk

Study website

<https://www.rampart-trial.org/>

Contact information

Type(s)

Public

Contact name

Mr Ben Smith

Contact details

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90 High Holborn, 2nd floor
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mrcctu.rampart@ucl.ac.uk

Type(s)

Public

Contact name

Ms Hanna Bryant

Contact details

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Additional identifiers**EudraCT/CTIS number**

2017-002329-39

IRAS number**ClinicalTrials.gov number**

NCT03288532

Secondary identifying numbers

RE06

Study information**Scientific Title**

An international investigator-led phase III multi-arm multi-stage multi-centre randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse

Acronym

RAMPART

Study objectives

Durvalumab is able to prevent tumour relapse by the inhibition of the programmed cell death 1 (PD-1)/ programmed death ligand 1 (PD-L1) pathway, which plays a critical role in tumour immune evasion.

Combination treatment with anti-CTLA4 agent tremelimumab increases immune response and anti-tumour activity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/01/2018, London Riverside Ethics Committee (Level 3 Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT; +44 (0)207 1048340, riverside.rec@hra.nhs.uk), ref 17/LO/1875

Study design

Multi-centre multi-arm multi-stage unblinded randomised controlled platform trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Resected primary renal cell carcinoma

Interventions

The trial will initially open with 3 research arms. The allocation ratio will be 3:2:2 with patients assigned centrally through block randomisation with a small number of clinically important stratification factors.

Arm A: The control arm is active monitoring after nephrectomy (observation through radiological means) for 1 year

Arm B: Durvalumab (1500 mg) administered 4 weekly for 1 year (13 cycles maximum) via intravenous infusion

Arm C: Durvalumab (1500 mg) administered as per arm B (13 cycles maximum) and tremelimumab (75 mg) on day 1 and week 4 visits (2 cycles) via intravenous infusion

The treatment duration is 1 year maximum. Once treatment is completed, patients will be seen at week 52, then 3 monthly up to the end of year 3, 6-monthly up to year 5 and annually thereafter.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Durvalumab, tremelimumab

Primary outcome measure

1. Disease Free Survival (DFS) will be assessed via radiological assessments through CT scans. DFS is defined as the interval from randomisation to first evidence of local recurrence, new primary RCC, distant metastases or death from any cause, whichever occurs first. All CT scans received will be further assessed by an independent review panel to ensure that progression has been reported correctly. Primary analysis for DFS will be carried out when:

Arm C vs Arm A

276 control arm events (approx 6.25 years) have occurred

Arm B vs Arm A

416 control arm events (approx 10.75 years) have occurred

DFS Interim analysis will be carried out at the following timepoints:

Arm B vs Arm A

Interim analysis 1 (overwhelming and lack-of-benefit) when 197 control arm events have occurred (approx 4.75 years)

Interim analysis 2 (overwhelming and lack-of-benefit) when 277 control arm events have occurred (approx 6.25 years)

Interim analysis 3 (overwhelming benefit) when 332 control arm events have occurred (approx 8 years)

Arm C vs Arm A:

Interim analysis 1 (overwhelming benefit and lack-of-benefit) when 198 control arm events have occurred (approx 4.75 years)

2. Overall Survival (OS) is another co-primary endpoint. OS is defined as all cause mortality, the time from randomisation to death from any cause (including RCC). For UK sites, survival status will also be collected against national mortality registers. Comparison of overall survival for Arm B vs Arm A will be carried out at approximately 20.5 years after trial commencement (triggered by 344 control arm OS events). For Arm C vs Arm A, overall survival will be assessed at approximately 13.25 years after trial commences (triggered by 238 control arm OS events)

Secondary outcome measures

Assessment of all secondary outcomes will take place at each follow-up visit at week 52, then 3 monthly up to the end of year 3, 6-monthly up to year 5 and annually thereafter.

1. Metastasis-free survival (MFS), defined as the interval from randomisation to first evidence of metastasis or death from RCC, measured via radiological means (CT scan with contrast)

2. RCC-specific survival time, defined as the time from randomisation to death from RCC, reported on trial-specific CRF

3. Quality of life, measured using quality of life questionnaires (EQ-5D and QLQ-C30 CRFs) at baseline, week 16, month 15, month 36 visits and at progression (if progression occurs before month 36)

4. Toxicity, reported on trial-specific CRF

5. Patient preferences for adjuvant immunotherapy information collected through the optional PAIR questionnaire completed at baseline, at the week 12 visit and the month 15 visit, or approximately 3 months after the last treatment visit if patient stops treatment early

Secondary outcome measures will be assessed after the primary analysis and therefore will be confirmed at a later date

Overall study start date

01/12/2017

Completion date

01/12/2037

Eligibility

Key inclusion criteria

Current inclusion criteria as of 17/07/2020:

1. Histologically proven RCC (all cell types of RCC are eligible, except for pure oncocytoma, collecting duct, medullary and transitional cell cancer [TCC]); no evidence of residual macroscopic disease on post-operative CT scan after resection of RCC. Patients with treated bilateral synchronous RCCs are eligible
2. At the start of recruitment patients with Leibovich score 3-11 will be eligible for randomisation. MRC CTU at UCL will monitor accrual and stop recruiting intermediate risk patients (Leibovich Score 3-5) after three years or when intermediate risk patients contribute 25% of the total accrual target, whichever is earlier. Recruitment of patients with Leibovich Score 6-11 will continue until the accrual target is reached
3. Patients should have had surgery at least 28 days but no more than 91 days prior to their randomisation date
4. Post-operative scans should be performed within 28 days prior to randomisation
5. Patients with microscopically positive resection margins after radical nephrectomy at the nephrectomy bed, renal vein or inferior vena cava are eligible provided the post-operative CT scan shows no evidence of residual macroscopic disease
6. WHO Performance Status 0 or 1
7. Patient has archival FFPE pathology tissue available, and agrees to provide at least one sample (FFPE tumour block from nephrectomy, or a minimum of 10 unstained slides), as well as a baseline EDTA blood sample for future translational research (this is separate to providing consent for TransRAMPART)
8. Adequate normal organ and marrow function
 - 8.1. Haemoglobin $\geq 9.0\text{g/dl}$ (transfusions will be allowed within 2 weeks prior to randomisation in order to achieve the entry criteria)
 - 8.2. Absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/\text{l}$ ($\geq 1,500$ per mm^3)
 - 8.3. Platelet count $\geq 100 \times 10^9$ ($\geq 100,000$ per mm^3)
 - 8.4. Bilirubin $\leq 1.5 \times \text{ULN}$ (This will not apply to subjects with confirmed Gilbert's syndrome (i.e., persistent or recurrent hyperbilirubinemia that is predominantly unconjugated in the absence of haemolysis or hepatic pathology), who will be allowed only in consultation with their physician)
 - 8.5. AST/ALT $\leq 2.5 \times \text{ULN}$
 - 8.6. Calculated Creatinine Clearance level $>40\text{mL/min}$ by Cockcroft Gault formula (using actual body weight)
9. 12-lead ECG on which QTcF must be <450 ms. In case of clinically significant ECG abnormalities, including a QTcF value ≥ 450 ms, two additional 12-lead ECGs should be obtained over a brief period (e.g., 30 minutes) to confirm the finding. Patients are only eligible if a QTcF of $<450\text{ms}$ is confirmed
10. Subjects must be ≥ 18 y of age
11. Written informed consent obtained from the patient
12. Both men and women enrolled in this trial must be in agreement with trial policy on contraception (Section 5.8.4) during the treatment phase of the study and 6 months afterwards. Egg donation, sperm donation and breastfeeding must be avoided
13. Evidence of post-menopausal status or negative serum HCG pregnancy test for female pre-menopausal patients. Women will be considered post-menopausal if they have been amenorrhoeic for 12 months without an alternative medical cause. The following age-specific requirements apply:
 - 13.1. Women < 50 y of age will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinising hormone and follicle-stimulating hormone levels in the post-menopausal range for the institution or underwent surgical sterilisation (bilateral oophorectomy or hysterectomy)
 - 13.2. Women ≥ 50 y of age will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of all exogenous hormonal treatments, had radiation-induced menopause with last menses > 1 y ago, had chemotherapy-induced

menopause with last menses > 1 y ago, or underwent surgical sterilisation (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy)

Previous inclusion criteria:

1. Histologically proven RCC (all cell types of RCC are eligible, except for pure oncocytoma, collecting duct, medullary and transitional cell cancer [TCC]); no evidence of residual macroscopic disease on post-operative CT scan after resection of RCC. Patients with treated bilateral synchronous RCCs are eligible
2. At the start of recruitment patients with Leibovich score 3-11 will be eligible for randomisation. MRC CTU at UCL will monitor accrual and stop recruiting intermediate risk patients (Leibovich Score 3-5) after three years or when intermediate risk patients contribute 25% of the total accrual target, whichever is earlier. Recruitment of patients with Leibovich Score 6-11 will continue until the accrual target is reached
3. Patients should have had surgery at least 28 days but no more than 91 days prior to randomisation date
4. Post-operative scans should be performed within 28 days prior to randomisation
5. WHO Performance Status 0 or 1
6. Patient has archival FFPE pathology tissue (FFPE tumour block from nephrectomy, or a minimum of 10 unstained slides) available as well as a baseline EDTA blood sample and agrees to provide a sample for future biomarker testing
7. Adequate normal organ and marrow function:
 - 7.1. Haemoglobin $\geq 9.0\text{g/dL}$ (transfusions will be allowed within 2 weeks prior to randomisation in order to achieve the entry criteria).
 - 7.2. Absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/\text{L}$ (≥ 1500 per mm^3)
 - 7.3. Platelet count $\geq 100 \times 10^9$ ($\geq 100,000$ per mm^3)
 - 7.4. Bilirubin $\leq 1.5 \times \text{ULN}$ (This will not apply to subjects with confirmed Gilbert's syndrome (i.e., persistent or recurrent hyperbilirubinemia that is predominantly unconjugated in the absence of haemolysis or hepatic pathology), who will be allowed only in consultation with their physician)
 - 7.5. AST/ALT $\leq 2.5 \times \text{ULN}$.
 - 7.6. Calculated Creatinine Clearance level $> 40\text{mL/min}$ by Cockcroft Gault formula (using actual body weight)
8. 12-lead ECG on which QTcF must be < 470 ms. In case of clinically significant ECG abnormalities, including a QTcF value > 470 ms, two additional 12-lead ECGs should be obtained over a brief period (e.g., 30 minutes) to confirm the finding
9. Current weight $\geq 40\text{kg}$
10. Subjects must be ≥ 18 years of age
11. Written informed consent obtained from the patient
12. Both men and women enrolled in this trial must be in agreement with trial policy on contraception during the treatment phase of the study and for 9 months afterwards. Egg donation, sperm donation and breastfeeding must be avoided
13. Evidence of post-menopausal status or negative urinary or serum pregnancy test for female pre menopausal patients. Women will be considered post-menopausal if they have been amenorrhoeic for 12 months without an alternative medical cause. The following age specific requirements apply:
 - 13.1. Women < 50 years of age will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinising hormone and follicle-stimulating hormone levels in the post-menopausal range for the institution or underwent surgical sterilisation (bilateral oophorectomy or hysterectomy)

13.2. Women ≥ 50 years of age will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of all exogenous hormonal treatments, had radiation-induced menopause with last menses >1 year ago, had chemotherapy induced menopause with last menses >1 year ago, or underwent surgical sterilisation (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1,750

Key exclusion criteria

Current exclusion criteria as of 17/07/2020:

1. Previous diagnosis of RCC
2. Metastatic or macroscopic residual disease
3. Patients with positive resection margins after partial nephrectomy
4. Patients with a single pulmonary nodule ≥ 5 mm diameter are not eligible unless the nodule has had a definite benign diagnosis. Patients with multiple small, less than 5 mm nodules may be eligible if nodules have been shown to be radiologically stable for at least 8 weeks.
5. Prior anticancer treatment (other than nephrectomy) for RCC
6. Any unresolved toxicity NCI CTCAE Grade ≥ 2 from previous anticancer therapy with the exception of alopecia, vitiligo, and the laboratory values defined in the inclusion criteria:
 - 6.1. Patients with Grade ≥ 2 neuropathy will be evaluated on a case-by-case basis after consultation with the Study Physician
 - 6.2. Patients with irreversible toxicity not reasonably expected to be exacerbated by treatment with durvalumab or tremelimumab may be included only after consultation with the Study Physician
7. History of another primary malignancy except for:
 - 7.1. Malignancy treated with curative intent and with no known active disease ≥ 5 y before the first dose of IP and of low potential risk for recurrence
 - 7.2. Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease
 - 7.3. Adequately treated carcinoma in situ without evidence of disease
8. History of leptomeningeal carcinomatosis
9. Concurrent enrolment in another clinical study, unless it is an observational (non-interventional) clinical study or during the follow-up period of an interventional study
10. Major surgical procedure (as defined by the Investigator) within 28 days prior to the start of treatment. Local surgery of isolated lesions for palliative intent is acceptable
11. Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab or tremelimumab, with the exceptions of intranasal and inhaled corticosteroids

or systemic corticosteroids at physiological doses, which are not to exceed 10 mg/day of prednisone, or an equivalent corticosteroid

12. Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease [e.g., colitis or Crohn's disease], diverticulitis [with the exception of diverticulitis], systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome [granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc]). The following are exceptions to this criterion:

12.1. Patients with vitiligo or alopecia

12.2. Patients with hypothyroidism (e.g., following Hashimoto syndrome) stable on hormone replacement

12.3. Any chronic skin condition that does not require systemic therapy

12.4. Patients without active disease in the last 5 years may be included but only after consultation with the RAMPART Trial Management Team

12.5. Patients with coeliac disease controlled by diet alone

13. A history of immunodeficiency syndrome. Please consult the MRC CTU at UCL on an individual basis if there is any uncertainty

14. History of allogeneic organ transplant

15. Uncontrolled intercurrent illness including, but not limited to:

15.1. Ongoing or active infection of any kind (patients who are exhibiting symptoms consistent with COVID-19, or who have tested positive, should not be randomised into the study until they are asymptomatic and at least 14 days after a positive test)

15.2. Symptomatic congestive heart failure

15.3. Uncontrolled hypertension

15.4. Unstable angina pectoris

15.5. Uncontrolled cardiac arrhythmia

15.6. Active peptic ulcer disease or gastritis

15.7. Active bleeding diatheses

15.8. Psychiatric illness or social situations that would limit compliance with study requirements or compromise the ability of the subject to give written informed consent

16. Active infection including:

16.1. Tuberculosis (clinical evaluation that includes clinical history, physical examination and radiographic findings, and TB testing in line with local practice)

16.2. Hepatitis B (known positive HBV surface antigen (HBsAg) result). Patients with a past or resolved HBV infection (defined as the presence of hepatitis B core antibody [anti-HBc] and absence of HBsAg) are eligible

16.3. Hepatitis C

16.4. Human immunodeficiency virus (positive HIV 1/2 antibodies). Note: Patients positive for hepatitis C (HCV) antibody are eligible only if polymerase chain reaction is negative for HCV RNA

17. Receipt of live attenuated vaccine within 30 days prior to the start of treatment. Note: Patients, if enrolled, should not receive live vaccine while receiving investigational medicinal product and up to 30 days after the last dose of investigational medicinal product

18. Pregnant or breastfeeding patients

19. Any condition that, in the opinion of the investigator, would interfere with evaluation of study treatment or interpretation of patient safety or study results

20. Known allergy or hypersensitivity to durvalumab or tremelimumab, or any of their excipients

21. Previous investigational medicinal product assignment in the present study

22. Clinically significant pneumonitis or fibrosis

Previous exclusion criteria:

1. Previous diagnosis of RCC
2. Metastatic or macroscopic residual disease
3. Patients with a single pulmonary nodule ≥ 5 mm diameter are not eligible unless the nodule has had a definite benign diagnosis. Patients with multiple small, less than 5 mm nodules may be eligible if nodules have been shown to be radiologically stable for at least 8 weeks
4. Prior anticancer treatment (other than nephrectomy) for RCC
5. Any unresolved toxicity NCI CTCAE Grade ≥ 2 from previous anticancer therapy with the exception of alopecia, vitiligo, and the laboratory values defined in the inclusion criteria:
 - 5.1. Patients with Grade ≥ 2 neuropathy will be evaluated on a case-by-case basis after consultation with the Study Physician.
 - 5.2. Patients with irreversible toxicity not reasonably expected to be exacerbated by treatment with durvalumab or tremelimumab may be included only after consultation with the Study Physician
6. Prior malignancy which in the opinion of the investigator has an estimated risk of recurrence in 5 years greater than 5%
7. History of leptomeningeal carcinomatosis
8. Concurrent enrolment in another clinical study, unless it is an observational (non interventional) clinical study or during the follow up period of an interventional study
9. Major surgical procedure (as defined by the Investigator) within 28 days prior to the start of treatment. Local surgery of isolated lesions for palliative intent is acceptable
10. Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab or tremelimumab, with the exceptions of intranasal and inhaled corticosteroids or systemic corticosteroids at physiological doses, which are not to exceed 10 mg/day of prednisone, or an equivalent corticosteroid
11. Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease [e.g., colitis or Crohn's disease], diverticulitis [with the exception of diverticulosis], systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome [granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc]). The following are exceptions to this criterion:
 - 11.1. Patients with vitiligo or alopecia
 - 11.2. Patients with hypothyroidism (e.g., following Hashimoto syndrome) stable on hormone replacement
 - 11.3. Any chronic skin condition that does not require systemic therapy
 - 11.4. Patients without active disease in the last 5 years may be included but only after consultation with the RAMPART Trial Management Team
 - 11.5. Patients with coeliac disease controlled by diet alone
12. A history of immunodeficiency syndrome. Please consult the MRC CTU at UCL on an individual basis if there is any uncertainty.
13. History of allogeneic organ transplant.
14. Uncontrolled intercurrent illness including, but not limited to:
 - 14.1. Ongoing or active infection
 - 14.2. Symptomatic congestive heart failure
 - 14.3. Uncontrolled hypertension
 - 14.4. Unstable angina pectoris
 - 14.5. Uncontrolled cardiac arrhythmia
 - 14.6. Active peptic ulcer disease or gastritis
 - 14.7. Active bleeding diatheses
 - 14.8. Psychiatric illness or social situations that would limit compliance with study requirements or compromise the ability of the subject to give written informed consent.
15. Active infection including:
 - 15.1. Tuberculosis (clinical evaluation that includes clinical history, physical examination and radiographic findings, and TB testing in line with local practice)

15.2. Hepatitis B (known positive HBV surface antigen (HBsAg) result)

15.3. Hepatitis C

15.4. Human immunodeficiency virus (positive HIV 1/2 antibodies). Patients with a past or resolved HBV infection (defined as the presence of hepatitis B core antibody [anti HBc] and absence of HBsAg) are eligible

Note: Patients positive for hepatitis C (HCV) antibody are eligible only if polymerase chain reaction is negative for HCV RNA

16. Receipt of live attenuated vaccine within 30 days prior to the start of treatment. Note: Patients, if enrolled, should not receive live vaccine while receiving investigational medicinal product and up to 30 days after the last dose of investigational medicinal product.

17. Pregnant or breastfeeding patients

18. Any condition that, in the opinion of the investigator, would interfere with evaluation of study treatment or interpretation of patient safety or study results

19. Known allergy or hypersensitivity to durvalumab or tremelimumab, or any of their excipients

20. Previous investigational medicinal product assignment in the present study

Date of first enrolment

20/12/2017

Date of final enrolment

30/03/2023

Locations

Countries of recruitment

Australia

England

France

Scotland

Spain

United Kingdom

Wales

Study participating centre

The Royal Marsden Hospital

Fulham Road

Chelsea

London

United Kingdom

SW3 6JJ

Study participating centre
Aberdeen Royal Infirmary
Intensive Care Unit
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
Bristol Haematology and Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Study participating centre
Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Castle Hill Hospital
Castle Road
Cottingham
United Kingdom
HU16 5JQ

Study participating centre

Charing Cross Hospital

Imperial College Healthcare NHS Trust
Fulham Palace Rd
Hammersmith
London
United Kingdom
W6 8RF

Study participating centre

Cheltenham General Hospital

Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre

The Christie

Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre

Churchill Hospital

Oxford University Hospitals NHS Foundation Trust
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre

Clatterbridge Cancer Centre

Clatterbridge Road
Bebington
Wirral
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CH63 4JY

Study participating centre
Colchester General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Glan Clwyd Hospital
Rhuddlan Rd
Rhyl
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LL18 5UJ

Study participating centre
Guy's Hospital
Great Maze Pond
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SE1 9RT

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

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Mount Vernon Hospital
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Study participating centre
Nottingham University Hospital
Hucknall Road
Nottingham

United Kingdom
NG5 1PB

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
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PO6 3LY

Study participating centre
Raigmore Hospital
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Inverness
United Kingdom
IV2 3UJ

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Royal Bournemouth Hospital
Castle Lane
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BH7 7DW

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London
United Kingdom
NW3 2QG

Study participating centre
Royal Marsden Hospital
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre

Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Southend University Hospital
Prittlewell Chase
Southend-on-Sea
United Kingdom
SS0 0RY

Study participating centre
South Tyneside District Hospital
Harton Ln
South Shields
United Kingdom
NE34 0PL

Study participating centre
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West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
St James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Sunderland Royal Hospital
Kayll Rd
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Torbay District Hospital
Lowes Bridge
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation

University College London

Sponsor details

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United Kingdom
WC1E 6BT
+44 (0)20 7679 2000
mrcctu.rampart@ucl.ac.uk

Sponsor type

University/education

Website

<https://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Industry

Funder Name

Kidney Cancer UK

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The protocol and all patient-related documents will be made available on the trial website (<https://www.rampart-trial.org/>) once approved by ethics committee and regulatory authority. Planned publication in a high-impact peer reviewed journal; articles will be open access in line with UCL publication policy.

Intention to publish date

01/12/2038

Individual participant data (IPD) sharing plan

The RAMPART Trial Management Team should be contacted in the first instance with any data release requests (mrcctu.rampart@ucl.ac.uk). Review of the request will be then escalated to the Trial Management Group and TSC for final approval. MRC CTU SOP on Data Sharing will be followed for the review and release process. Requests to release control arm data will be considered at any point during the trial but data release requests for the entire dataset (including treatment arms) will not be granted until the primary end-points have been reached and published. Consent will be obtained by patients prospectively and data release is subject to successful execution of the relevant contract.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/09/2021	21/09/2021	Yes	No
Protocol article		01/09/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No