

Patient Initials Date of Birth

Patient Name

Hospital Number

To be completed prior to randomisation to aid in checking patient eligibility for RAMPART.

Please use this list to record when an assessment for patient eligibility has been completed or a criteria has been met.

Please note that this is for site use only; a copy is not required to be sent to the RAMPART team.

Staging & Screening - Tick or fill boxes when completed

Pre-randomisation CT scan (please tick)
(Thorax, abdomen and pelvis)

ⓘ A post-operative CT scan be used if it's within 28 days of randomisation date.

Leibovich score (provide scores)

Score

Pathological T category of primary tumour
(pT1a=0, pT1b=2, pT3a-4=4)

Regional lymph node status
(pNx/pN0=0, pN1-pN2=2)

Tumour size
(<10cm=0, ≥10=1)

Nuclear grade
(Grade 1=0, Grade 2=0, Grade 3=1,
Grade 4= 3)

Histological tumour necrosis
(No=0, Yes=1)

Leibovich score (sum of above scores)

ⓘ Please ensure that the Leibovich score calculation is correct before randomisation. Only patients belonging to the intermediate or high risk groups are eligible.

Leibovich score 0-2 = Low risk
Leibovich score 3-5 = Intermediate risk
Leibovich score 6 or more = High risk

If there are any doubts about the score, please contact the MRC CTU.

Surgery date at least 28 days and no more than 91 days prior to randomisation. (please tick)

Histopathology (please tick)

ⓘ All cell types of RCC are eligible, except for pure oncocytoma, collecting duct, medullary and transitional cell cancer. Tick if eligible.

WHO performance score (provide score)

ⓘ To be eligible, WHO score must be 0 or 1

Archival FFPE pathology tissue (please tick)

ⓘ If archival FFPE pathology tissue is unavailable, a minimum of 10 unstained slides can also be used. Patient must also provide a baseline EDTA sample.

Adequate normal organ and marrow function (please tick)

ⓘ Details of clinical blood tests to determine adequate normal organ and marrow function can be found overleaf.

ECG (please tick)

ⓘ QTcF value must be <450ms. For more details see protocol.

Blood Assessments - Tick when completed

① The following test results must fall within a certain range to display adequate normal organ and marrow function:
 Haemoglobin ≥ 9.0 g/dL
 Absolute neutrophil count $\geq 1.5 \times 10^9/L$ (≥ 1500 per mm^3)
 Platelet count $\geq 100 \times 10^9$ ($\geq 100,000$ per mm^3)
 Bilirubin $\leq 1.5 \times$ ULN
 AST/ ALT $\leq 2.5 \times$ ULN
 Creatinine clearance level >40 mL/min

Clinical Chemistry

- | | |
|---|--|
| <input type="checkbox"/> Alanine aminotransferase (ALT) | <input type="checkbox"/> Lactate dehydrogenase (LDH) |
| <input type="checkbox"/> Albumin | <input type="checkbox"/> Lipase |
| <input type="checkbox"/> Alkaline phosphatase (ALP) | <input type="checkbox"/> Magnesium |
| <input type="checkbox"/> Amylase | <input type="checkbox"/> Potassium |
| <input type="checkbox"/> Aspartate aminotransferase (AST) | <input type="checkbox"/> Random cortisol |
| <input type="checkbox"/> Bicarbonate | <input type="checkbox"/> Serum pregnancy test |
| <input type="checkbox"/> Calcium | <input type="checkbox"/> Sodium |
| <input type="checkbox"/> Chloride | <input type="checkbox"/> Thyroid stimulating hormone (TSH) |
| <input type="checkbox"/> Creatinine | <input type="checkbox"/> Total bilirubin |
| <input type="checkbox"/> Creatinine clearance | <input type="checkbox"/> Total protein |
| <input type="checkbox"/> Gamma glutamyltransferase (GGT) | <input type="checkbox"/> Urea/ Blood urea nitrogen |
| <input type="checkbox"/> Glucose | <input type="checkbox"/> Uric acid |
| <input type="checkbox"/> Hepatitis serologies | |

Haematology

- | | |
|--------------------------------------|---|
| <input type="checkbox"/> Basophils | <input type="checkbox"/> MCV |
| <input type="checkbox"/> Eosinophils | <input type="checkbox"/> Monocytes |
| <input type="checkbox"/> Haematocrit | <input type="checkbox"/> Neutrophils |
| <input type="checkbox"/> Haemoglobin | <input type="checkbox"/> Platelet count |
| <input type="checkbox"/> Lymphocytes | <input type="checkbox"/> Red blood cell count (RBC) |
| <input type="checkbox"/> MCH | <input type="checkbox"/> Total white cell count (WBC) |
| <input type="checkbox"/> MCHC | |
| <input type="checkbox"/> | |

Eligibility criteria - Tick to confirm patient meets each criterion

- | | |
|--|--------------------------|
| Eligible histologically proven renal cell carcinoma (RCC)..... | <input type="checkbox"/> |
| Leibovich score 3 to 11..... | <input type="checkbox"/> |
| Surgery at least 28 days but no more than 91 days prior to randomisation..... | <input type="checkbox"/> |
| WHO performance status 0 or 1..... | <input type="checkbox"/> |
| Adequate normal tissue and marrow function..... | <input type="checkbox"/> |
| ECG QTcF < 450ms..... | <input type="checkbox"/> |
| Subjects must be ≥ 18 years of age..... | <input type="checkbox"/> |
| Written informed consent obtained..... | <input type="checkbox"/> |
| Both men and women must use adequate contraception during treatment and up to 6 months afterwards..... | <input type="checkbox"/> |
| Evidence of post-menopausal status or negative serum HCG pregnancy test..... | <input type="checkbox"/> |
| Willing to comply with follow up schedule..... | <input type="checkbox"/> |
| No prior diagnosis of RCC..... | <input type="checkbox"/> |
| | <input type="checkbox"/> |

