ANZUP 1606

RAMPART Trial News

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Welcome to the first RAMPART newsletter

RAMPART opened its first site, Box Hill Hospital on the 29 September 2021, closely followed by Calvary Mater Newcastle on the 8 October 2021, Sunshine Coast University Hospital and Campbelltown Hospital in November 2021. We have recently activated our fifth site, Concord Repatriation General Hospital on 21 March 2022 and working to open more sites in the coming months. During this short period of time, RAMPART has 6 participants enrolled! A huge thank you and congratulations to all involved for your hard work and efforts in reaching this milestone!

A message from Study Chair: Prof Ian Davis

"RAMPART has been in development for at least ten years, so it is wonderful finally to see it open and recruiting well in Australia through ANZUP. Many of us participated in SORCE previously and have contributed to industry-sponsored adjuvant RCC studies also, so this workflow should not come as much of a crunch. We need to make sure we have effective systems for flagging patients in clinics, through multidisciplinary meetings, and through local referring clinicians and health services.

The KeyNote-564 trial gave convincing evidence for benefit of pembrolizumab in RCC at high risk of recurrence, so we can expect interest from the community. I think RAMPART is a better design and a more interesting question. Keep an eye on the newsletter for more information coming through about a planned amendment, and the potential capping of the intermediate risk cohort. Meanwhile, thanks again for your support, and a final reminder: recruitment is competitive, so this is your chance to outshine all your colleagues!"

Study team introduction

Study Chair: Professor Ian Davis
Deputy Chair: A/Prof Craig Gedye

ANZUP Team (study sponsor):
Chair: Ian Davis
CEO: Marg McJannett
Head of Research Operations: Nisha Rana
Clinical Trials Project Manager: Thomas Cusick
ANZUP Clinical Research Fellows –
Shalini Subramaniam, Danka Zebic and Blossom Mak

International Sponsor:
University College London (UCL)
Co-ordinated by: Medical Research Council Clinical Trials Unit (MRC CTU)
RAMPART trial website: https://www.rampart-trial.org/

CTC Team:
Clinical Lead – Martin Stockler
Project Manager – Izabella Pokorski
Trial Coordinator – Lenna Lai
Translational Research team – Sonia Yip and Estefania Martino Echarri

Contact us: rampart.study@sydney.edu.au - the trial mailbox for all your study related questions or trials@anzup.org.au for any sponsor related queries.

ANZUP Cancer Trials Group Limited

What is RAMPART?

Renal Adjuvant MultiPle Arm Randomised Trial

(RAMPART): 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

Primary objectives

1. Disease Free Survival (DFS), comparison between all treatment Arms, does Arm B or Arm C increase DFS as compared with Arm A
2. Overall Survival, comparison between all treatment Arms, does Arm B or Arm C increase DFS as compared with Arm A

Secondary objectives are:

3. Metastasis Free Survival (MFS), defined as the interval from randomisation to first evidence of or death from RCC
4. RCC specific survival time, defined as the time from randomisation to death from RCC
5. Quality of life
6. Toxicity
7. Patient preferences for adjuvant immunotherapy

Exploratory Objective:
To collect blood and tissue samples for defining biological responses to durvalumab and for identifying candidate markers (e.g. PD-L1 expression) that may correlate with likelihood of clinical benefit.

RAMPART is an investigator-initiated study sponsored and led by ANZUP. This trial is funded by Kidney Cancer UK, University College London and by an educational grant from Astra Zeneca. ANZUP receives valuable infrastructure support from the Australian Government through Cancer Australia.

Randomisation Process

Approximately 1,750 patients will be recruited to the initial three arm design.

Recruitment across the current three study arms will be:

- Arm A - 750 patients
- Arm B - 500 patients
- Arm C - 500 patients

If the patient is deemed eligible on all criteria, please forward all required paper-based CRF on GalaxKey to **rampart.study@sydney.edu.au** and **mrcctu.rampart@ucl.ac.uk**.

Reminder for all sites to check access to Galaxkey, Pharmacists to check access to Drug Shipment Management System (DSMS).

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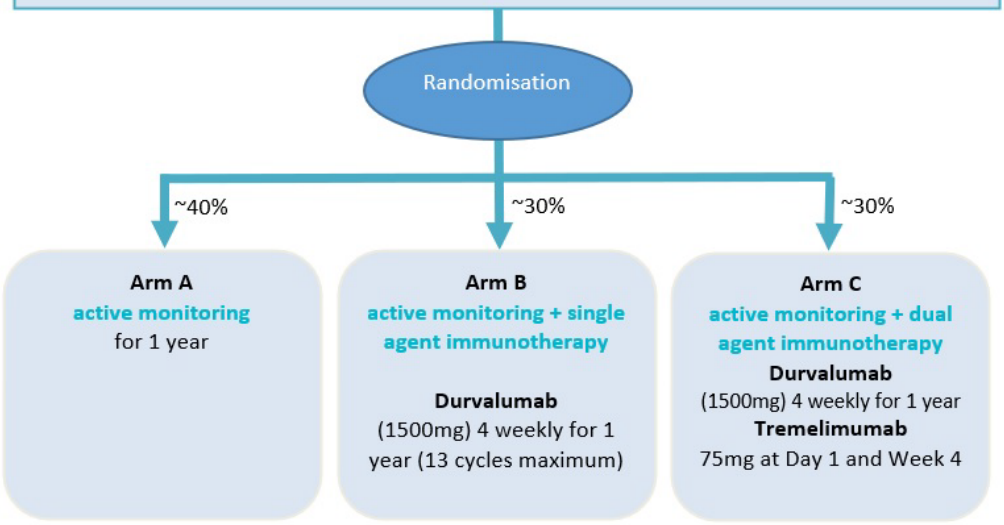
Patient Eligibility

Please refer patients with…

1. Resected renal cell carcinoma, with no evidence of residual macroscopic disease after surgery
2. Intermediate to high risk i.e. Leibovich score* 3-11
3. Resected ipsilateral adrenal metastases allowed
4. 3-6 weeks after surgery (randomisation within 3 months of surgery)
5. Microscopically involved resection margins ok if post-op CT shows no evidence of disease
6. Without major co-morbidities

**see below for Leibovich risk scoring*



- *Patients will be randomly assigned in a ratio of 3:2:2 (Arm A:B:C)*

RISK SCORING

FEATURE		SCORE
Pathological T category of primary tumour	pT1a	0
	pT1b	2
	pT2	3
	pT3a-4	4
Regional lymph node status	pNx or pN0	0
	pN1-pN2	2
Tumour size	<10cms	0
	10cms or more	1
Nuclear grade	1 or 2	0
	3	1
	4	3
Histological tumour necrosis	No	0
	Yes	1

RISK GROUPS

SCORES	GROUP
0-2	Low-risk
3-5	Intermediate risk
6 or more	High-risk

Serious Adverse Event Reporting

Please ensure Serious Adverse Events (SAEs) are reported to the RAMPART team within 24 hours of you becoming aware of the event.

Report all Adverse Events, from time of consent and up to 120 days post-treatment via the AE Log (Form 06) or SAE CRF (Form 13). If in doubt, please contact the RAMPART study team for assistance.

Reminder: SAE reporting is completed through our Paper CRF. Please scan the paper CRF and send it on GalaxKey to **rampart.study@sydney.edu.au** and **mrcctu.rampart@ucl.ac.uk.**

Please answer all fields prior to submitting the report on InForm if possible.

Once all available information has been entered, click the "Submit" button to ensure the CTC Team receive the report.

In collaboration with:

Thank you for your ongoing support of the RAMPART Trial.
If you have any questions, please feel free to contact the study team on rampart.study@sydney.edu.au

RAMPART key contacts

- **Clinical trial operations, CTC E:** rampart.study@sydney.edu.au
- **Sponsor queries (payments, contracts) ANZUP E:** trials@anzup.org.au
- **Trial information:** https://anzup.org.au/clinical-trial/rampart/