

# Clinical Trials Network e-Newsletter



February 2025

## Only have 60 seconds?

### Site Spotlights

- John Flynn Private Hospital joins global phase III heart failure clinical trial
- Wollongong Private Hospital has completed their last patient visit for the ANTHEM Study
- Peninsula Private Hospital opened first cardiology trial, FocalFlex Study.
- Prindara Private Hospital successful completion of their Short Notice Assessment under NCTGF.
- Greenslopes Private Hospital [recent case report](#) on aortic valve replacement in second trimester pregnancy.

**New publication** in the Lancet authored by Dr Marco Matos, medical oncologist at Pindara Private Hospital. [Durvalumab with or without bevacizumab with transarterial chemoembolisation in hepatocellular carcinoma \(EMERALD-1\): a multiregional, randomised, double-blind, placebo-controlled, phase 3 study.](#)

**The CARE Network** - Unites over 50 hospitals and clinical services across Australia and internationally, including four Ramsay sites, and conducts multi-site naturalistic research into treatment success in interventional psychiatry. View one of the Networks [latest publications here](#) or view the [CARE Network website here](#).

**Latest Rapid Research Video** - [Professor Jeanne Tie on RHRF Funded study 'Detect-PM'](#).

**Ramsay Clinic Albert Road** - Graduate Nurse, Christine Raymer speaks out her experience in the Clinical Trials & Research Unit. [View here](#)

**2 x 1 hour free Biostatistics Consultations available.** [Register your interest here](#)

**15+ New publications** from our Doctors, VMO's and RHRF grant recipients.

## Site Spotlights

### John Flynn Private Hospital Joins Global Phase III Heart Failure Clinical Trial

In December, John Flynn Private Hospital conducted its first-ever cardiology site initiation visit, marking its participation in a global Phase 3 heart failure clinical trial.

As the second site activated in Australia, John Flynn Private Hospital is currently leading national recruitment with four participants already screened and several more screening visits planned in the coming weeks. The study has a strict eligibility criteria, and no participants have been enrolled for study treatment yet. The hospital, along with the rest of the country, is still searching for the first eligible participant in Australia.

The clinical trial is led by Dr. Ashok Gangasandra Basavaraj, a dedicated and experienced interventional cardiologist passionate about providing world-class care. This trial investigates a potential new treatment for heart failure patients with a left ventricular ejection fraction of

Heart failure is the leading cause of hospitalization for patients over 65 years globally, placing a significant strain on healthcare systems. With limited treatment options currently available, this clinical trial could pave the way for a new foundational therapy.

This international study, sponsored by Janssen Research & Development, LLC, is designed to evaluate the safety and effectiveness of JNJ-77242113 compared with placebo in participants with moderately to severely active ulcerative colitis. Wollongong Private Hospital successfully recruited 1 patient to the study, and completed the final patient visit on 16th January 2025. The trial is due to run through to mid 2026.

Peninsula Private Hospital is participating in their first Cardiology Trial, the FocalFlex Study, under the guidance of Professor Han Ling. The FocalFlex Study is a global, interventional device study that aims to assess the performance of the TactiFlex Duo Ablation Catheter, Sensor Enabled (SE). The catheter is designed to treat patients with paroxysmal atrial fibrillation and offers more flexible treatment options by allowing physicians to use either Pulsed Field Ablation (PFA) or radiofrequency (RF) depending on the specific needs of the case.

Peninsula Private Hospital Clinical Trials & Research Unit successfully recruited and treated 2 patients before recruitment closed due to faster than expected recruitment worldwide.

Congratulations to Pindara Private Hospital, and to Emma Langshaw and the Clinical Trials & Research Unit team, for successfully passing their recent Short Notice Accreditation Assessment. The assessment ensures compliance with the NSQHS Standards and quality improvement strategies.

A case report from Greenslopes Private Hospital outlines the 'Repair of Ascending Aortic Aneurysm with Mechanical Aortic Valve Replacement in the Second Trimester of Pregnancy'.

The report details the case of a 34 year old female who presented at 18 weeks gestation complaining of mild breathlessness on exertion and fatigue.

[Read the full report here.](#)

# Repair of Ascending Aortic Aneurysm with Mechanical Aortic Valve Replacement in Second Trimester of Pregnancy

Craven, A<sup>1</sup>, Morze, J<sup>1</sup>, Roberts, S<sup>2</sup>, Ura M<sup>3</sup>

<sup>1</sup>Heart Valve Institute, Cleveland Clinic, Cleveland, OH; <sup>2</sup>Obstetrics and Gynecology, Cleveland Clinic, Cleveland, OH; <sup>3</sup>Cardiothoracic Surgery, Cleveland Clinic, Cleveland, OH

**BACKGROUND**

Aortic aortic valve (AV) and thoracic aortic valve replacement (AVR) are performed during pregnancy with the lowest reported mortality (1). However, cardiac surgery and cardiopulmonary bypass (CPB) in addition to the anticoagulation changes, like uterine risks to mother and fetus which require special consideration. In this case, we outline the multidisciplinary decision-making approach led by patient experts, MHA, complications and outcomes in a pregnant woman undergoing ascending aortic aneurysm repair and aortic valve replacement at 19 weeks gestation.

**POST PARTUM AORTIC COMPLICATIONS**

Post-operative, postpartum compression aortitis were used for the management of these cases. The patient was managed on prophylactic heparin sodium 5000 units bid for 18 hours after the surgery. As per usual post-Aortic Valve Replacement protocol, Heparin 5000 units was commenced at 24 hours post procedure and slowly titrated. Her INR reached therapeutic range on Day 4 post surgery and heparin 2000 units was ceased.

Hemoglobin nadir post surgery was 7.4g/L on Day 2. As she was asymptomatic, no transfusions were given. Her hemoglobin in the weeks following slowly recovered without intervention.

She was changed to therapeutic Enoxaparin 40mg twice daily in the weeks after surgery. She was 11 days post surgery and she was understandably concerned about the risk of fetal brain hemorrhage. In addition, her INR was off her baseline sub-therapeutic due to her reluctance to receive the heparin. She was counseled that although her INR was off her baseline, her Enoxaparin dose required gradual increments to continue to achieve recommended peak and trough anti-Xa levels. In the few weeks of her pregnancy, Enoxaparin treatment was slow, more than 100mg total.

A fetal MRI was performed at 30 weeks gestation which showed no abnormally, specifically no evidence of intracranial hemorrhage.

**POST PARTUM BLEEDING COMPLICATION**

Under the direction of the MHA, the patient was discharged on Day 20 of Enoxaparin was 2.4 hours after surgery and 12 hours after the last heparin dose. She was discharged on day 17 hours after surgery. A healthy baby girl, 3.4kg, 48cm, 34cm was delivered with Apgars of 8 at 1 minute and 10 at 5 minutes. She was discharged on Day 20.

**EXAMINATION AND INVESTIGATIONS**

Cardiovascular examination revealed a regular pulse without radio/radio or radio-distant delay and non-tender with a wide pulse pressure. The jugular venous pressure was not elevated and heart sounds were dual with an innocent holosystolic murmur audible over the aortic valve area. There was no clear carotid bruit and there was no pedal edema.


An echocardiogram was performed at 19 weeks gestation which showed an aneurysmal ascending aorta with effacement of the subvalvular junction. The aortic valve was bicuspid with severe central regurgitation. There was no evidence of the presence of aortic coarctation and visualized portions of the thoracic aorta were normal.

**SURGERY AND ANAESTHETIC**

At 19 weeks gestation, an open heart surgery by sternotomy. Openly cannulated aortocaval ascending aorta was done with a standard distal anastomosis. The aortic aneurysm was also opened and the surrounding tissue, making the procedure difficult. Prior to the surgery, the valve-sparing aortic root replacement and isolated AVR operation were considered as options. However, at surgery, one of the aortic leaflets was severely calcified and the aortic root was severely dilated.

**CONCLUSION**

Ascending aortic aneurysm repair and aortic valve replacement during pregnancy is a high-risk procedure. The multidisciplinary approach led by patient experts, MHA, complications and outcomes in a pregnant woman undergoing ascending aortic aneurysm repair and aortic valve replacement at 19 weeks gestation.



**References**

1. Craven A, Morze J, Roberts S, Ura M. Repair of Ascending Aortic Aneurysm with Mechanical Aortic Valve Replacement in Second Trimester of Pregnancy. *Ann Thorac Surg*. 2020;110(1):e100-101. doi:10.1016/j.athoracsurg.2019.09.025

*"Cardiac surgery has been traditionally avoided in pregnancy due high rates of foetal demise, and concerns about neurocognitive development of the foetus during periods of maternal circulatory arrest."*

# The CARE Network

**The Ramsay Hospital Research Foundation supports The CARE Network - a pioneering initiative to elevate clinical services in Neurostimulation and Interventional Psychiatry.**

The CARE Network is dedicated to promoting high-quality clinical care through collaboration and innovation. By uniting over 50 hospitals and clinical services across Australia and internationally, including four Ramsay sites, the network fosters a community committed to excellence in patient care. One of the network's core strengths is its commitment to supporting clinicians. By providing free resources and standardised clinical measures, the CARE Network empowers member hospitals and clinics to deliver the best possible care to their patients.

The Network also conducts multi-site naturalistic research to uncover factors that influence treatment success in interventional psychiatry. This collaborative approach ensures that findings are robust and applicable across diverse clinical settings. View one of the Networks [latest publications here](#) which outlines the revision of an instrument to assess side effects from Ketamine interventions, which is used at clinics within the Network, including Ramsay's Northside Clinic.

We are excited about the future of the CARE Network and its potential to transform clinical practice in neurostimulation and interventional psychiatry. Together, we are making strides towards a brighter, healthier future for all.

To learn more about the CARE Network or to know how to get involved, visit [CARE Network](#)



*Dr Donel Martin*

*"Research derived from data collected using the CARE Network framework has played an important role in informing government policies at the state and national level"*

## Staff Highlights

### Clinical Trial Unit Manager, Emily Vasiljevski, awarded Ramsay Health Care Scholarship

Last year, Emily (John Flynn Private Hospital Clinical Trials & Research Unit Manager) obtained a National RHC Scholarship to host an in-person GCP workshop at John Flynn Private Hospital.

This is the first time that this opportunity has been offered to RHC employees at John Flynn Private Hospital and is a unique learning opportunity for employees.

The training is scheduled to take place on Tuesday 20th May, on International Clinical Trials Day.

Congratulations Emily.





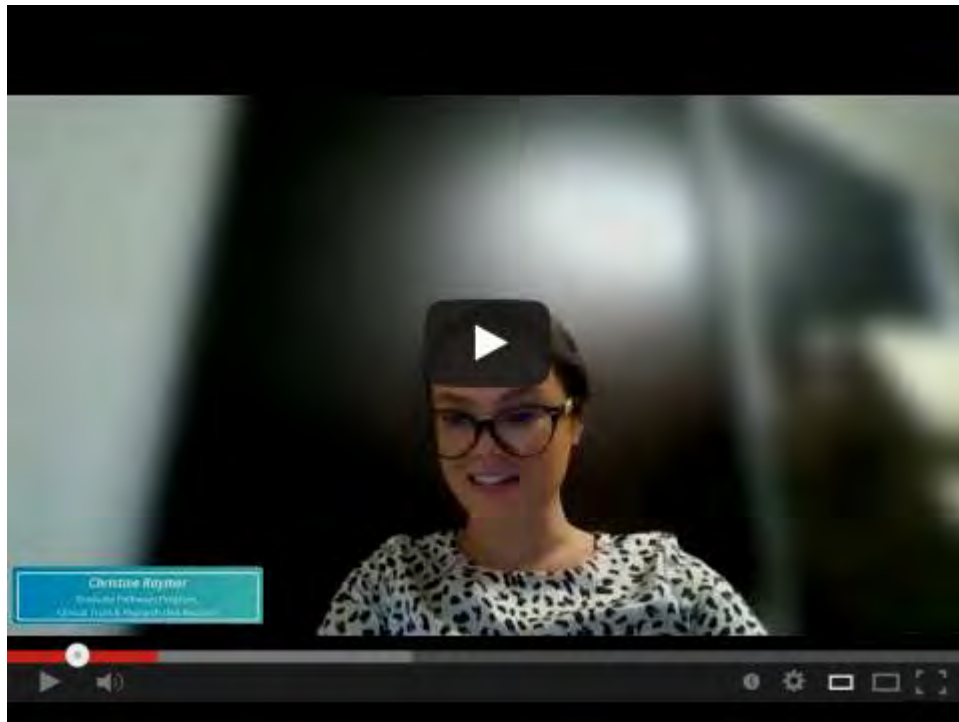
# Graduate Pathways Program- Clinical Trials Unit Rotation

The Ramsay Health Care Graduate Pathways Program offers registered and enrolled nurses an opportunity to complete a rotation in one of the Clinical Trials & Research Units.

Christine Raymer is in her second year of the program and is completing her Clinical Trials Unit rotation at Ramsay Clinic Albert Road.

*"I would really promote for nurses to jump into research, at least give it a go. Whether it's for three months or six months and just see what the research world has got to offer because it's something that you don't really learn much about at university. So if there's an opportunity there most definitely grab it." - Christine Raymer*

[Listen to Christine speak about her experience.](#)



## RHRF Accepted as MRFF Eligible Organisation

We are thrilled to announce that the Ramsay Hospital Research Foundation (RHRF) has registered and been accepted as a Medical Research Future Fund (MRFF) Eligible Organisation.

**This means that RHRF can support Ramsay VMO's through the application process for MRFF funding, and can manage and administer the funds for research in accordance with MRFF standards.**

This collaboration offers a streamlined process for Ramsay VMO's to apply for funding and conduct research.

The objective of the MRFF is to improve the health and wellbeing of Australians. RHRF supports this objective by undertaking medical research and medical innovation activities, ensuring that our efforts contribute significantly to the advancement of healthcare and patient outcomes nationwide.

If you have any questions, contact RHRF grants team at [RHRFgrants@rhfrf.org.au](mailto:RHRFgrants@rhfrf.org.au)



*Pictured: members of the Ramsay Hospital Research Foundation team, and Ramsay National Research Unit.*

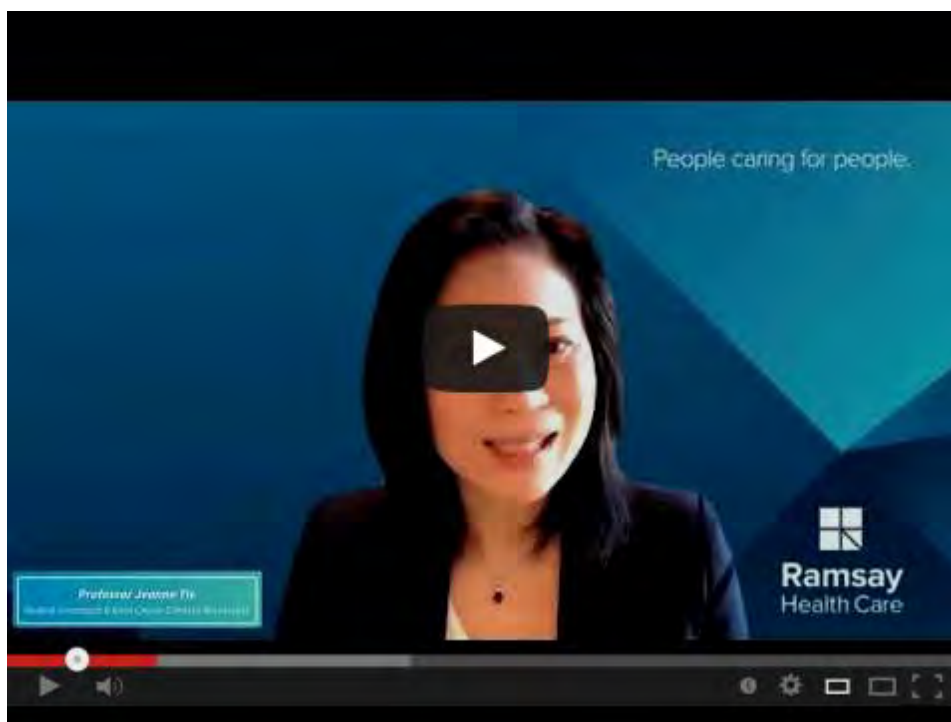
## Latest Rapid Research Video Released

Watch the latest Rapid Research Video released by Ramsay Hospital Research Foundation outlining the Detect-PM Study.

Led by Professor Jeanne Tie, the RHRF funded project '**Detect-PM**' aims to use state-of-the-art technology to analyse cancer DNA in abdominal fluid in bowel cancer patients. With the intention to accurately identify peritoneal disease at the micro-metastatic stage, the team hopes to successfully predict future relapse, providing an opportunity for earlier intervention.

The team have recently recruited their first patient to the study. Congratulations to all involved.

[Listen to Professor Jeanne Tie here.](#)



## Biostatistics and other Research Consultations Available

**Ramsay provide a range of consultations to assist you in conducting high quality research.**

These consultations are for Ramsay accredited practitioners or Ramsay staff involved in or contemplating conducting research at Ramsay facility.

We offer consultations in the following

Register for Biostatistics  
Consultation



Register for Ramsay Ethics &  
Governance Consultation



Register for RHRF Grant  
Writing Consultation



## Published Research

Congratulations to several of our Doctors, VMO's and RHRF grant recipients on their recent publications. We are fortunate to see contributions from researchers who actively participate in our Clinical Trials & Research Units as well as from those affiliated with Ramsay sites more broadly.

**Marco Matos - Pindara Private Hospital**

[Durvalumab with or without bevacizumab with transarterial chemoembolisation in hepatocellular carcinoma \(EMERALD-1\): a multiregional, randomised, double-blind, placebo-controlled, phase 3 study.](#) *Lancet*.

**Jaswinder Samra & Anubhav Mittal - North Shore Private Hospital**

[Promising biomarker panel to monitor therapeutic efficacy of neoadjuvant chemotherapy in pancreatic cancer patients.](#) - *Eur J Clin Invest*.

**Hayden Young - Joondalup Health Campus**

[Haptoglobin phenotype and levels in type 2 diabetes and effects of fenofibrate](#) - *J Diabetes Investig*.

**Brad Jongeling & Desiree Silva - Joondalup Health Campus**

[Influence of maternal and infant technology use and other family factors on infant development.](#) - *BMC Pediatr*.

**Robert Evans - Joondalup Health Campus**

[Modern multiligament knee injury surgical reconstruction techniques can achieve excellent knee function and patient satisfaction, with low complication rates.](#) *Knee Surg Sports Traumatol Arthrosc*.

**Ali Tafreshi - Wollongong Private Hospital**

[Medicine Access Programmes: what do patients think - a patient-reported outcome study on ribociclib in metastatic breast cancer in Australia.](#) *Intern Med J*.

**Scott Popham - John Flynn Private Hospital**

[Critical care unit bed availability and postoperative outcomes: a multinational cohort study.](#) *Anaesthesia*.

**Chandra Rath, Saravanan Muthusamy & Shripada Rao - Joondalup Health Campus**

[Lactobacillus rhamnosus GG as a probiotic for preterm infants: a strain specific systematic review and meta-analysis.](#) *Eur J Clin Nutr*.

**Tim Papadopoulos - Westmead Private Hospital**

[There Is no Universal Standard of Beauty.](#) *Aesthetic Plast Surg*.

**Rashmi Ghanpur - Warringal Private Hospital**

[The Renal Effect of 20% Human Albumin Solution Fluid Bolus Therapy in Patients After Cardiac Surgery. A Secondary Analysis of the HAS FLAIR II Randomized Clinical Trial.](#) *J Cardiothorac Vasc Anesth*.

**Luke McGarry & Rajitha Gunaratne - Joondalup Health Campus**

[Medial buttress plate use in neck of femur fracture fixations: A systematic review.](#) *Injury*.

**Laura Beesley & Dalia Moreno - Ramsay Clinic Northside**

**Colleen Loo - RHRF CRR Grant Recipient - The CARE Network**

[Safety outcomes of ketamine for treatment-resistant depression in clinical settings and development of the ketamine side effect tool-revised \(KSET-R\).](#) *Psychiatry Res*.

**Mohammad Boushnak - Joondalup Health Campus**

[Percutaneous treatment of de Quervain's disease using Sono-Instruments®: A feasibility study.](#) *J Hand Surg Eur*

**Desiree Silva - Joondalup Health Campus**

[Feasibility of home-based urine collection in children under 5 years in the ORIGINS birth cohort study: mixed method protocol and sample completion results.](#) *BMC Nutr*.

**Simone Steel - Peninsula Private Hospital**

[Real-world impact of pembrolizumab availability for deficient mismatch repair metastatic colorectal cancer.](#) *Intern Med J*.

**Luke McGarry & Rajitha Gunaratne - Joondalup Health Campus**

[Medial buttress plate use in neck of femur fracture fixations: A systematic review.](#) *Injury*.

**Angie Monk - Joondalup Health Campus**


[Patient Blood Management Program Implementation and Assessment Tool: Measuring Compliance With Guidelines and World Health Organization 2021 Policy Brief.](#) *Anesth Analg*.

**Alex Baer, Malcolm Anastasius, Chris Choong, Peter Hansen & Ravinay Bhindi - North Shore Private Hospital**

[The Innovative Use of Concurrent Transcaval Access and the BASILICA Procedure to Facilitate Transcatheter Aortic Valve Replacement \(TAVR\).](#) *CJC Open*.


## Interested in getting involved?

Email us at [info@rhrf.org.au](mailto:info@rhrf.org.au) 

Visit our Website 

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Have something you'd like to share in Ramsay Clinical Trials Network E-News?

Submit a story 

Sent to: [bartholomewalexandra@rhrf.org.au](mailto:bartholomewalexandra@rhrf.org.au)

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Ramsay Health Care Australia, Level 7, Tower B 7 Westbourne Street, St Leonards NSW 2065, Australia