



RATIONAL Platform Trial RATIONALISE Trial

Role of Antibiotic Therapy or Immunoglobulin On iNfections in hAematoLogy

Newsletter June 2024

Welcome to the first newsletter of the RATIONALISE trial and RATIONAL platform trial.

Study Updates

The RATIONALISE trial is now active at six sites, with 15 participants enrolled. Thank you to all site investigators and coordinators for your efforts, and a special thanks to Concord for leading recruitment with 11 participants. RATIONALISE is the first domain of the new RATIONAL platform trial, which has received ethics approval and preparing to open additional domains to recruitment in the next quarter.

Website

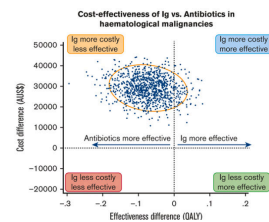
We have a website! Visit rationalisetrials.com to find out more about the RATIONALISE trial and its substudies. Details about the RATIONAL platform trial will be coming soon.



Pilot Trial Outcomes & Economic Evaluation Published

RATIONAL pilot trial Role of Antibiotic Therapy or IVIg on Infection Prevention in Hematology			
Population	Interventions	Outcomes	Conclusion
<p>Acquired hypogammaglobulinemia secondary to hematological malignancy 63 patients</p>	<p>Immunoglobulin (0.4g/kg/4-weekly IV) <p>Prophylactic Antibiotics (trimethoprim-sulfamethoxazole 1600mg/800mg daily)</p> </p>	<p>Similar proportion of participants remained on their allocated treatment arm at 12 months: 70% in immunoglobulin vs 71% antibiotics, $P= .77$</p> <p>Rates of major infection were similar in each intervention: lower quartile time to first major infection: 11.1 m in immunoglobulin vs 9.7 m in antibiotics, $P= .20$</p>	<p>Supports the feasibility of a phase III trial</p>

Outcomes of the RATIONAL pilot trial are now published in Blood Advances (8(7): 1787–95)



An economic analysis of the pilot is also available in Blood Advances (8(9): 2259–67)



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