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TRiCS·IV

Transfusion Requirements in Cardiac Surgery

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Austin HEALTH

TRICS IV: international multi-centre RCT

Hypothesis	Higher Hb (liberal transfusion) superior (in terms of organ function (heart, brain, kidney) + mortality at 6 moths) than lower Hb (restrictive transfusion)
Study population	≤65yo) undergoing CPB for cardiac surgery
Sub-study	Observational study
	Relationship between Iron storage (including hepcidin) + DAAH at 30 days
Methodology	Liberal Hb threshold: ≤95g/L OR / ICU (≤85g/L Ward) vs Restrictive Hb threshold (<75g/L
	Physiologic triggers allowed to increase transfusion threshold by 5g/L in both arms

Trial progress

Initial

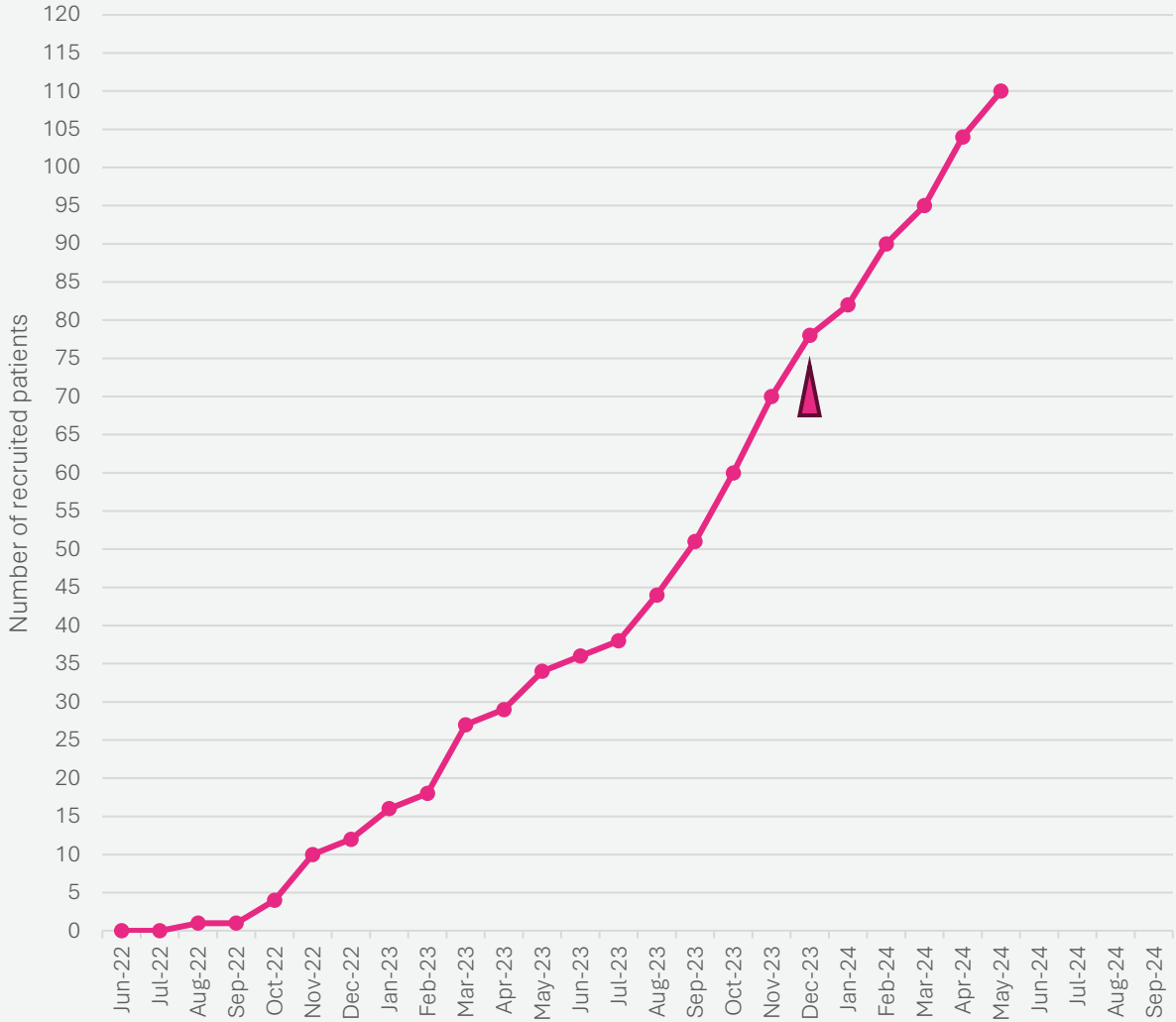
Global Target **n = 1440**	• (CIHR 2019-2022)
Australian Target n = 500	• (MRFF ICTC 2020-2023)
Superiority trial 85% power	• Bayesian, 1.5% attrition rate

Update

UK target n = 320	• (NIHR grant 2022)
New Global Target **n = 1802**	• Total number recruited = **781** randomised (early July 2024)
Revised Australian target n = 300	• Total number in Australia is **130** randomised (end of July 2024)
Superiority trial 90% power	• Frequentist, 4.5% attrition rate

Australian progress

MRFF Progress	Awarded 2019 for 2020-2023	
	Extension for COVID granted for 8 months (early 2024)	
	1st patient August 2021	
	Recommendation to terminate grant March 2024	"not achieved 15% target within 12 months"
	Appeal successful June 2024, funded to early 2025	



Sites

Activated	Number
Flinders Medical Centre	28
The Alfred	25
Austin Health	24
Royal Adelaide Hospital	19
Royal Melbourne Hospital	10
St Vincent's Hospital Melbourne	7
Gold Coast University Hospital	7
Victorian Heart Hospital	7
Royal Prince Alfred Hospital	3
Prince of Wales Hospital	0
Westmead Hospital	0

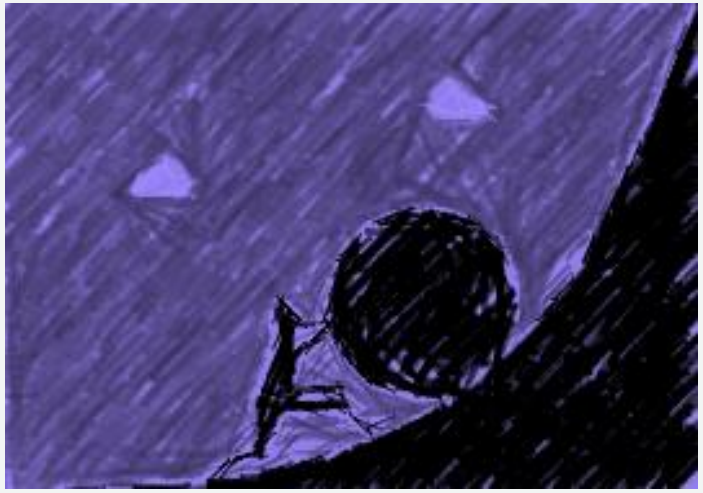
Under governance
Barwon Health
Townsville Hospital

Lessons learned

Boutique cohort + complex data = Less Interest	Previous success does NOT equal Future success (TRICS III is NOT the same as TRICS IV)	Get Research nurses involved with creating the database.	Money greases the wheels

• Abundant cohort + simple data = Lots of interest!	• Pay attention to detail regarding differences.
	  • Subject eligibility -≤ 65 + EuroScore I is different cohort
	  • Physiologic triggers
	  • Database is different
		• Appoint a good database manager.
		• Automatic data queries are exhausting - use smarter algorithms instead of querying everything.
			• Hospitals will preference trials that pay research nurses.
			• Be aware of trial fatigue

Tips to overcome recruitment challenges



Identify barriers to recruitment

- E.g. Surgeon's opinions may have shifted

Be creative at finding solutions / Share solutions with other centres.

- E.g. Challenging Euroscore I definition of pulmonary hypertension (PASP >60mmHg) in Manual of Operations by using Euroscore II definition (PASP >31mmHg)

Simplify protocol

- E.g. removing required data, making it optional and not mandatory.

Provide better remuneration / Re-look at budget

- Particularly if under-recruiting

Personalise connections with sites (COVID highly depersonalised)