



***Single Use Negative Pressure Dressing For Reduction In
Surgical Site Infection Following Emergency Laparotomy***

Trial Progress Report

Date report prepared: 11/05/2021

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Section 1: Significant milestones

Table 1: Milestone summary

Date first centre opened to recruitment (activated):	09-Jan-2020 (John Hunter Hospital)
Current recruitment/total recruitment:	293* Australia / 804 Total**
Date first participant randomised:	23-Jan-2020 (John Hunter Hospital)

* 304 randomisations; ineligible participants removed from total

** As recorded in CHaRT Randomisation Service 11/05/2021

Centres opened to recruitment

Centre	PI	Activated	Closed to Recruitment
John Hunter Hospital	Peter Pockney Stephen Smith	09-Jan-2020	16-Dec-2020
Flinders Medical Centre	David Watson	13-Feb-2020	16-Dec-2020
Royal Adelaide Hospital	Tarik Sammour	29-Jan-2020	16-Dec-2020
Fiona Stanley Hospital	Toby Richards	17-Jan-2020	16-Dec-2020
Sunshine Coast University Hospital	Bree Stephensen	05-May-2020	16-Dec-2020
St John of God Subiaco Hospital	Patrick Tan	25-May-2020	16-Dec-2020
Gosford Hospital	Amanda Dawson	14-Jun-2020	16-Dec-2020
Sir Charles Gairdner Hospital	Jonathan Foo	23-Jun-2020	16-Dec-2020
Belmont Hospital	Peter Pockney	17-Sep-2020	16-Dec-2020
Concord Repatriation Hospital	Henry Cheung	08-Jul-2020	01-Feb-2021
Gold Coast University Hospital	Phil Townend	05-Nov-2020	01-Feb-2021
Austin Hospital	Vijayaragavan Muralidharan	08-Oct-2020	01-Feb-2021

Centres discontinued / not activated (HREC Notified 17-Dec-2020)

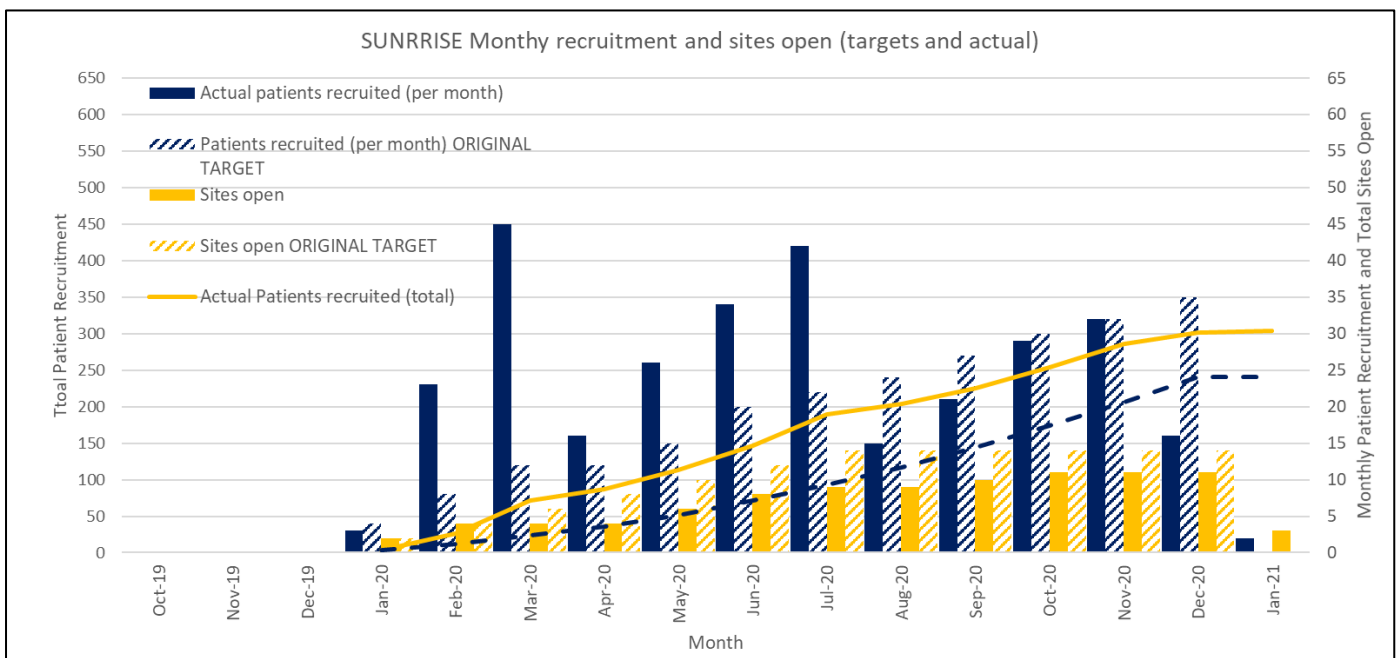
Centre	PI
Westmead Hospital	Henry Pleass
Footscray Hospital	Julian Choi
Sunshine Hospital	Julian Choi
Princess Alexandra Hospital	Harsheet Sethi
Toowoomba Hospital	Damian Fry
Joondalup Health Campus	Paul Salama

Section 2: Recruitment update

- 12 sites opened to recruitment by 05-Nov-2020
- 9/12 sites closed to recruitment on 16-Dec-2020
- Remaining 3 sites closed to recruitment on 01-Feb-2021

A. Recruitment by month

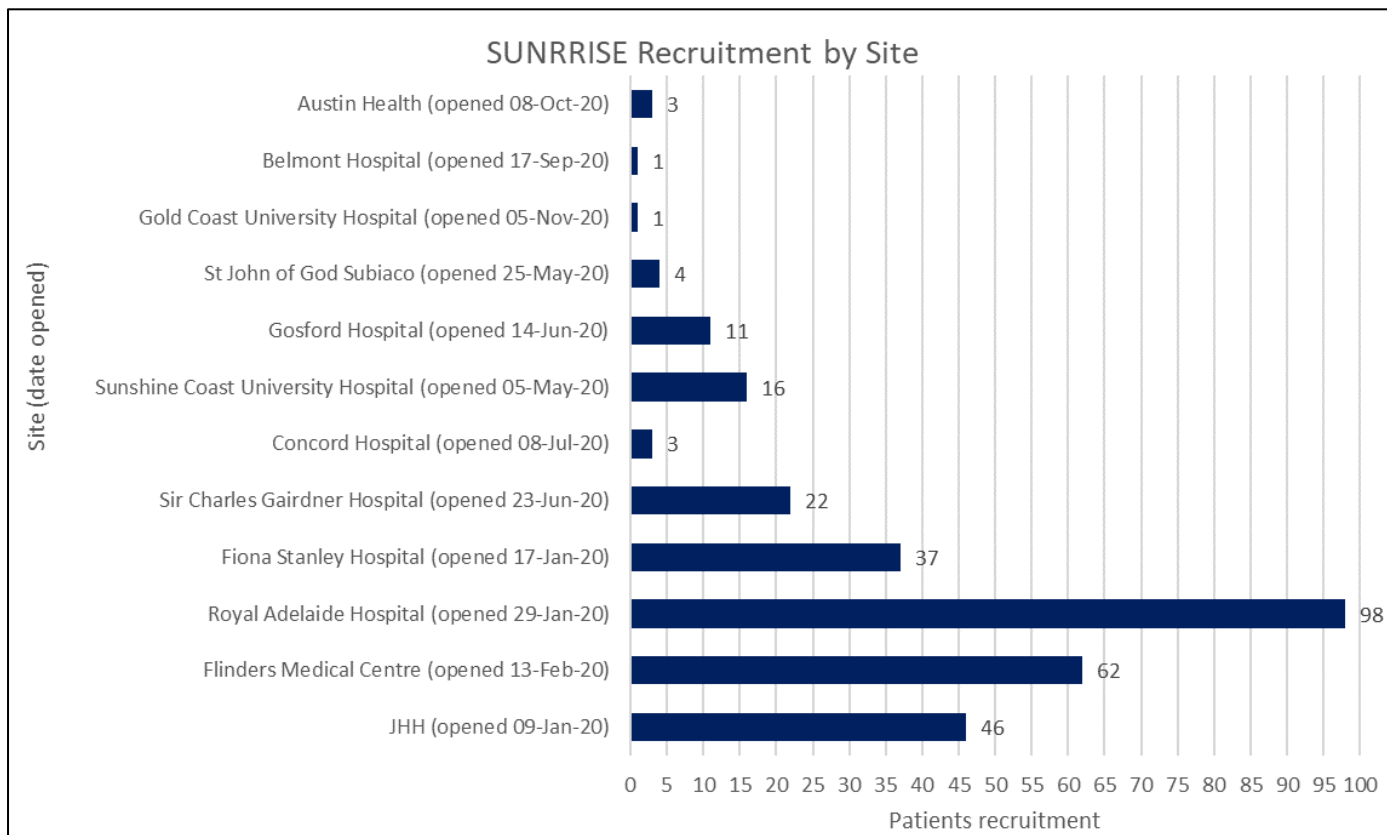
Figure 1: Recruitment by month*



* Total randomisations displayed; ineligible participants not removed

B. Recruitment by site

Figure 2: Recruitment by site*



* Total randomisations displayed; ineligible participants not removed

Section 4: Data completeness (including attrition)

Table 2: Overall form return rates

	Randomisation form	Consent form	In-theatre form	Wound Assessment Day 7	Wound Assessment Day 30	Return to Theatre form	Patient Discontinuation form	Baseline EQ-5D	Baseline SF-12	Patient Diary	Day 7 EQ-5D	Day 7 SF-12	Day 14 QoL	Day 21 QoL	Day 30 EQ-5D	Day 30 SF-12	Bluebelle WHQ	Patient Diary (Cont. involvement)	PI Declaration Form
Total Expected	292	293	292	291	290	4	13	292	292	288	287	287	287	287	287	287	287	10	304
Total Received	292	293	292	290	289	4	13	251	252	150	183	182	134	130	179	177	124	1	0
% Received	100%	100%	100%	99.7%	99.7%	100%	100%	86.0%	86.3%	52.1%	63.8%	63.4%	46.7%	45.3%	62.4%	61.7%	43.2%	10.0%	0.0%
Will Not Receive	0	0	0	1	1	0	0	41	40	119	84	85	131	136	83	83	136	5	0
% Accounted For	100%	100%	100%	100%	100%	100%	100%	100%	100%	88.8%	90.1%	90.1%	85.9%	86.1%	87.7%	86.8%	82.1%	20.0%	0.0%
John Hunter Hospital	100%	100%	100%	100%	100%	100%	100%	100%	100%	94.7%	100%	100%	95.7%	94.4%	97.5%	97.5%	95.5%	0.0%	
Fiona Stanley Hospital	100%	100%	100%	100%	100%	100%	100%	100%	100%	39.3%	73.3%	73.3%	37.0%	33.3%	65.5%	63.3%	50.0%	0.0%	
Royal Adelaide Hospital	100%	100%	100%	100%	100%	n/a	100%	100%	100%	100%	86.7%	86.7%	96.5%	96.6%	87.3%	87.3%	87.5%	100%	
Flinders Medical Centre	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	96.7%	96.6%	100%	100%	93.1%	93.1%	94.1%	n/a	
Sunshine Coast University Hospital	100%	100%	100%	100%	100%	100%	n/a	100%	100%	100%	75.0%	75.0%	100%	100%	66.7%	62.5%	57.1%	n/a	
St John of God Subiaco	100%	100%	100%	100%	100%	n/a	n/a	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	n/a	
Gosford Hospital	100%	100%	100%	100%	100%	n/a	n/a	100%	100%	88.9%	100%	100%	71.4%	100%	90.0%	90.0%	83.3%	n/a	
Sir Charles Gairdner Hospital	100%	100%	100%	100%	100%	n/a	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	n/a	
Concord Hospital	100%	100%	100%	100%	100%	n/a	n/a	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	n/a	
Belmont Hospital	100%	100%	100%	100%	100%	n/a	n/a	100%	100%	100%	100%	100%	100%	100%	100%	100%	n/a	n/a	
Austin Health	100%	100%	100%	100%	100%	n/a	n/a	100%	100%	n/a	100%	100%	n/a	n/a	100%	100%	100%	n/a	
Gold Coast University Hospital	100%	100%	100%	100%	100%	n/a	100%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	

Table 3: Overall query generation and return rates

	Number of participants	Total queries generated	Queries per participant	Number resolved	Number outstanding (Resolved = No/Blank)
Overall	304	1119	3.7	1103	16
John Hunter Hospital	46	223	4.8	220	3
Fiona Stanley Hospital	37	133	3.6	128	5
Royal Adelaide Hospital	98	269	2.7	262	7
Flinders Medical Centre	62	202	3.3	201	1
Sunshine Coast University Hospital	16	77	4.8	77	0
St John of God Subiaco	4	16	4.0	16	0
Gosford Hospital	11	39	3.5	39	0
Sir Charles Gairdner Hospital	22	113	5.1	113	0
Concord Hospital	3	14	4.7	14	0
Belmont Hospital	1	5	5.0	5	0
Austin Health	3	24	8.0	24	0
Gold Coast University Hospital	1	4	4.0	4	0

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