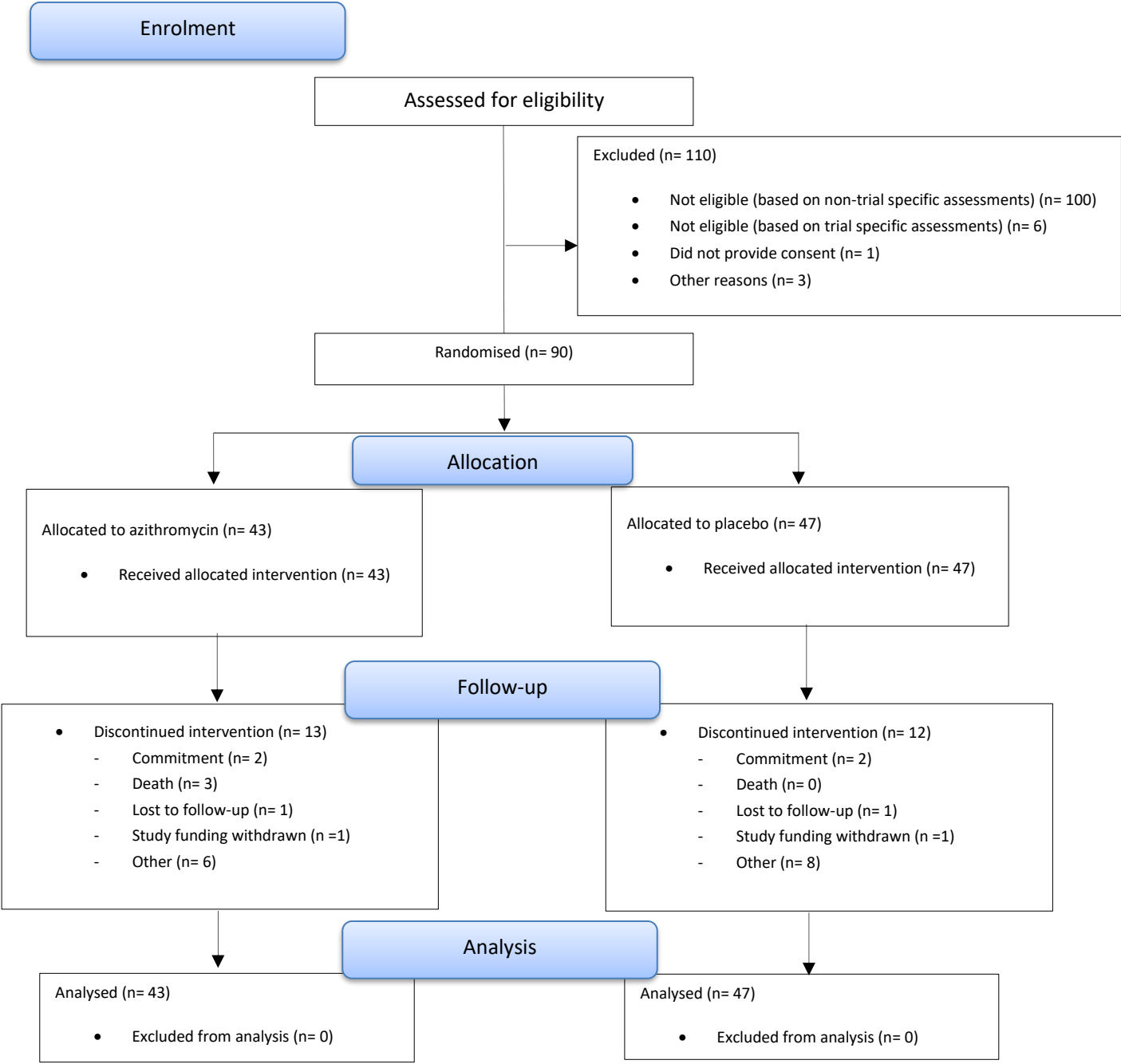


Completeness of follow-up



Baseline characteristics

	UK			Australia			Overall		
	Azithromycin	Placebo	Total	Azithromycin	Placebo	Total	Azithromycin	Placebo	Total
Age (years)									
n	11	17	28	32	30	62	43	47	90
mean	11.3	8.6	9.6	9.5	8.6	9	9.9	8.6	9.2
standard deviation	4.5	4.29	4.49	4.52	4.19	4.34	4.53	4.18	4.37
Minimum	3	3	3	3	3	3	3	3	3
Median	13	8	9.5	9	7.5	8	10.5	8	9
Maximum	16	17	17	17	16	17	17	17	17
Missing	0	0	0	1	0	1	1	0	1
Age (years): n(%)	(n=11)	(n=17)	(n=28)	(n=32)	(n=30)	(n=62)	(n=43)	(n=47)	(n=90)
Children (2-11 years)	3 (27.3)	13 (76.5)	16 (57.1)	19 (59.4)	21 (70)	40 (64.5)	22 (51.2)	34 (72.3)	56 (62.2)
Adolescents (12-17 years)	8 (72.7)	4 (23.5)	12 (42.9)	12 (37.5)	9 (30)	21 (33.9)	20 (46.5)	13 (27.7)	33 (36.7)
Missing	0	0	0	1	0	1	1	0	1
Weight (kg)									
n	11	17	28	32	30	62	43	47	90

	UK			Australia			Overall		
	Azithromycin	Placebo	Total	Azithromycin	Placebo	Total	Azithromycin	Placebo	Total
mean	35.4	26.5	30	29.9	29	29.5	31.4	28.1	29.6
standard deviation	15.68	13.15	14.61	12.28	14	13.06	13.31	13.61	13.49
Minimum	13.7	11.1	11.1	12.6	14.2	12.6	12.6	11.1	11.1
Median	33.8	24.8	25.9	28	24.5	25.6	30	24.5	25.8
Maximum	68.1	58.8	68.1	65	66	66	68.1	66	68.1
Missing	0	0	0	2	0	2	2	0	2
Gender: n(%)	(n=11)	(n=17)	(n=28)	(n=32)	(n=30)	(n=62)	(n=43)	(n=47)	(n=90)
Male	9 (81.8)	10 (58.8)	19 (67.9)	15 (46.9)	18 (60)	33 (53.2)	24 (55.8)	28 (59.6)	52 (57.8)
Female	2 (18.2)	7 (41.2)	9 (32.1)	15 (46.9)	12 (40)	27 (43.5)	17 (39.5)	19 (40.4)	36 (40)
Missing	0	0	0	2	0	2	2	0	2

Ethnicity

Ethnicity UK	Azithromycin	Placebo	Total
Parent identifies child to be n(%)	(n=11)	(n=17)	(n=28)
White - British	9 (81.8%)	9 (52.9%)	18 (64.3%)
Any other Mixed/Multiple ethnic group	0 (0%)	2 (11.8%)	2 (7.1%)
Asian or Asian British - Bangladeshi	0 (0%)	2 (11.8%)	2 (7.1%)
Black, African, Caribbean or Black British - African	2 (18.2%)	0 (0%)	2 (7.1%)
Other Ethnic Group	0 (0%)	4 (23.5%)	4 (14.3%)

Ethnicity AUS	Azithromycin	Placebo	Total
Parent identifies child to be n(%)	(n=32)	(n=30)	(n=62)
Aboriginal	4 (12.5%)	1 (3.3%)	5 (8.1%)
Non-Indigenous	19 (59.4%)	21 (70%)	40 (64.5%)
Unknown	4 (12.5%)	5 (16.7%)	9 (14.5%)
Missing	5 (15.6%)	3 (10%)	8 (12.9%)

Primary Outcome

	Treatment group	N	Hospitalised with LRTI n (%)	Not hospitalised with LRTI n (%)	Absolute risk difference*	95% CI	Relative risk**	95% CI
Overall	Azithromycin	30	11 (36.7)	19 (63.3)	0.11	-0.12, 0.33	1.43	0.68, 2.97
	Placebo	35	9 (25.7)	26 (74.3)				
	Total	65	20 (30.8)	45 (69.2)				
	Treatment group	N	Hospitalised with LRTI n (%)	Not hospitalised with LRTI n (%)	Absolute risk difference*	95% CI	Relative risk**	95% CI
UK	Azithromycin	8	4 (50)	4 (50)	0.28	-0.16, 0.72	2.25	0.55, 9.17
	Placebo	9	2 (22.2)	7 (77.8)				
	Total	17	6 (35.3)	11 (64.7)				
	Treatment group	N	Hospitalised with LRTI n (%)	Not hospitalised with LRTI n (%)	Absolute risk difference*	95% CI	Relative risk**	95% CI
Australia	Azithromycin	22	7 (31.8)	15 (68.2)	0.05	-0.21, 0.31	1.18	0.49, 2.85
	Placebo	26	7 (26.9)	19 (73.1)				
	Total	48	14 (29.2)	34 (70.8)				

* Azithromycin- Placebo / ** Azithromycin/ Placebo

Safety Data

Non-serious adverse events/reactions

	System Organ Class	Azithromycin	Placebo	Total
		Events n	Events n	Events n
Overall	Blood and lymphatic system disorders	1	0	1
	Cardiac disorders	0	1	1
	Gastrointestinal disorders	62	98	160
	General disorders and administration site conditions	13	18	31
	Infections and infestations	21	45	66
	Injury, poisoning and procedural complications	4	5	9
	Investigations	5	6	11
	Metabolism and nutrition disorders	0	1	1
	Musculoskeletal and connective tissue disorders	1	0	1
	Nervous system disorders	13	8	21
	Product issues	1	1	2
	Psychiatric disorders	3	1	4
	Renal and urinary disorders	0	1	1
	Respiratory, thoracic and mediastinal disorders	20	31	51
	Skin and subcutaneous tissue disorders	7	18	25
	Surgical and medical procedures	2	7	9
	Total	153	241	394
UK	Blood and lymphatic system disorders	1	0	1
	Cardiac disorders	0	1	1
	Gastrointestinal disorders	18	17	35
	General disorders and administration site conditions	10	15	25

	System Organ Class	Azithromycin	Placebo	Total
		Events n	Events n	Events n
	Infections and infestations	11	35	46
	Injury, poisoning and procedural complications	4	3	7
	Investigations	4	5	9
	Metabolism and nutrition disorders	0	1	1
	Musculoskeletal and connective tissue disorders	1	0	1
	Nervous system disorders	7	4	11
	Renal and urinary disorders	0	1	1
	Respiratory, thoracic and mediastinal disorders	10	22	32
	Skin and subcutaneous tissue disorders	1	3	4
	Surgical and medical procedures	1	5	6
	Total	68	112	180
AUS	Gastrointestinal disorders	44	81	125
	General disorders and administration site conditions	3	3	6
	Infections and infestations	10	10	20
	Injury, poisoning and procedural complications	0	2	2
	Investigations	1	1	2
	Nervous system disorders	6	4	10
	Product issues	1	1	2
	Psychiatric disorders	3	1	4
	Respiratory, thoracic and mediastinal disorders	10	9	19
	Skin and subcutaneous tissue disorders	6	15	21
	Surgical and medical procedures	1	2	3
	Total	85	129	214

Serious adverse events/reactions

	System Organ Class	Azithromycin	Placebo	Total
		Events n	Events n	Events n
Overall	Gastrointestinal disorders	8	9	17
	General disorders and administration site conditions	1	2	3
	Infections and infestations	12	10	22
	Injury, poisoning and procedural complications	1	0	1
	Investigations	1	1	2
	Metabolism and nutrition disorders	0	1	1
	Missing	1	4	5
	Nervous system disorders	3	3	6
	Product issues	1	0	1
	Psychiatric disorders	1	1	2
	Respiratory, thoracic and mediastinal disorders	11	14	25
	Surgical and medical procedures	5	4	9
	Total	45	49	94
UK	General disorders and administration site conditions	1	0	1
	Infections and infestations	2	1	3
	Missing	0	2	2
	Respiratory, thoracic and mediastinal disorders	0	1	1
	Surgical and medical procedures	1	0	1
	Total	4	4	8
AUS	Gastrointestinal disorders	8	9	17
	General disorders and administration site conditions	0	2	2
	Infections and infestations	10	9	19

	System Organ Class	Azithromycin	Placebo	Total
		Events n	Events n	Events n
	Injury, poisoning and procedural complications	1	0	1
	Investigations	1	1	2
	Metabolism and nutrition disorders	0	1	1
	Missing	1	2	3
	Nervous system disorders	3	3	6
	Product issues	1	0	1
	Psychiatric disorders	1	1	2
	Respiratory, thoracic and mediastinal disorders	11	13	24
	Surgical and medical procedures	4	4	8
	Total	41	45	86