

NAPiC DMC Safety report

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Introduction

This is the safety report for the Data Monitoring Committee meeting in the NNAPiC trial. The data are based on an export from the Viedoc electronic data capture system time stamped “_20231220_085025”. There are totally 377 patients in the database. Of these 43 are confirmed excluded from the safety set.

All patients in the Safety Analysis Set

First we report on the total number of subjects except those who we know are excluded. There are 334 in this dataset with 166 in the placebo arm and 168 in the amoxicillin arm.

AE Summary

Table 1: Summary of Adverse Events

Parameter	Placebo (N=166)	Amoxicillin (N=168)
Number of AEs	[193] 95 (57.2%)	[152] 85 (50.6%)
Number of patients with any AEs?	95 (57.2%)	85 (50.6%)
Number of patients with one AE	53 (31.9%)	50 (29.8%)
Number of patients with two AE	15 (9%)	19 (11.3%)
Number of patients with three or more AEs	27 (16.3%)	16 (9.5%)
Number of SAEs	[4] 4 (2.4%)	[4] 4 (2.4%)
Number of patients with any SAEs?	4 (2.4%)	4 (2.4%)

The numbers are [Number of events] Number of patients (percentage of patients), or Number of patients (percentage of patients)

Table 2: Adverse Events by System Organ Class and Preferred term

System Organ Class	Preferred Term	Placebo (N=166)	Amoxicillin (N=168)
Eye disorders	#Total	[1] 1 (0.6%)	
	Eye discharge	[1] 1 (0.6%)	
Gastrointestinal disorders	#Total	[139] 78 (47%)	[94] 60 (35.7%)
	Abdominal pain upper	[1] 1 (0.6%)	
	Breath odour	[1] 1 (0.6%)	
	Constipation	[1] 1 (0.6%)	[1] 1 (0.6%)

System Organ Class	Preferred Term	Placebo (N=166)	Amoxicillin (N=168)
	Diarrhoea	[65] 53 (31.9%)	[59] 50 (29.8%)
	Gingival pain		[1] 1 (0.6%)
	Infantile spitting up		[1] 1 (0.6%)
	Nausea		[2] 2 (1.2%)
	Oral mucosal eruption	[2] 2 (1.2%)	[2] 2 (1.2%)
	Post-tussive vomiting	[12] 10 (6%)	[2] 2 (1.2%)
	Tongue blistering	[1] 1 (0.6%)	
	Tongue eruption	[1] 1 (0.6%)	
	Vomiting	[55] 37 (22.3%)	[26] 18 (10.7%)
General disorders and administration site conditions	#Total	[9] 8 (4.8%)	[2] 2 (1.2%)
	Condition aggravated		[2] 2 (1.2%)
	Gait disturbance	[1] 1 (0.6%)	
	Pyrexia	[8] 7 (4.2%)	
Immune system disorders	#Total		[1] 1 (0.6%)
	Immunodeficiency		[1] 1 (0.6%)
Infections and infestations	#Total	[7] 7 (4.2%)	[11] 11 (6.5%)
	Anal abscess	[1] 1 (0.6%)	
	Candida nappy rash		[1] 1 (0.6%)
	Conjunctivitis	[1] 1 (0.6%)	
	Ear infection	[2] 2 (1.2%)	
	Gastroenteritis	[2] 2 (1.2%)	[1] 1 (0.6%)
	Genital infection fungal		[1] 1 (0.6%)
	Hand-foot-and-mouth disease	[1] 1 (0.6%)	
	Otitis media		[2] 2 (1.2%)
	Respiratory tract infection		[3] 3 (1.8%)
	Rhinovirus infection		[1] 1 (0.6%)
	Sepsis		[1] 1 (0.6%)
	Viral rash		[1] 1 (0.6%)
Injury, poisoning and procedural complications	#Total	[1] 1 (0.6%)	
	Traumatic tooth displacement	[1] 1 (0.6%)	
Investigations	#Total	[1] 1 (0.6%)	
	Platelet count increased	[1] 1 (0.6%)	
Metabolism and nutrition disorders	#Total	[1] 1 (0.6%)	
	Poor feeding infant	[1] 1 (0.6%)	
Nervous system disorders	#Total	[1] 1 (0.6%)	[4] 4 (2.4%)
	Dysgeusia		[1] 1 (0.6%)
	Febrile convulsion		[3] 3 (1.8%)
	Tremor	[1] 1 (0.6%)	
Psychiatric disorders	#Total	[1] 1 (0.6%)	
	Insomnia	[1] 1 (0.6%)	
Respiratory, thoracic and mediastinal disorders	#Total	[4] 4 (2.4%)	[2] 2 (1.2%)
	Bronchial obstruction	[1] 1 (0.6%)	
	Dyspnoea	[1] 1 (0.6%)	[1] 1 (0.6%)

System Organ Class	Preferred Term	Placebo (N=166)	Amoxicillin (N=168)
Skin and subcutaneous tissue disorders	Epistaxis		[1] 1 (0.6%)
	Nasal flaring	[1] 1 (0.6%)	
	Tachypnoea	[1] 1 (0.6%)	
	#Total	[27] 25 (15.1%)	[38] 32 (19%)
	Dermatitis atopic	[1] 1 (0.6%)	[3] 3 (1.8%)
	Dermatitis diaper		[4] 4 (2.4%)
	Miliaria	[1] 1 (0.6%)	[2] 2 (1.2%)
	Rash	[23] 23 (13.9%)	[28] 22 (13.1%)
Surgical and medical procedures	Urticaria	[2] 2 (1.2%)	[1] 1 (0.6%)
	#Total	[1] 1 (0.6%)	
	Hospitalisation	[1] 1 (0.6%)	

Serious Adverse Events

Table 3: Serious Adverse Events by System Organ Class and Preferred term

System Organ Class	Preferred Term	Placebo (N=166)	Amoxicillin (N=168)
Immune system disorders	#Total		[1] 1 (0.6%)
	Immunodeficiency		[1] 1 (0.6%)
Infections and infestations	#Total	[1] 1 (0.6%)	[2] 2 (1.2%)
	Anal abscess	[1] 1 (0.6%)	
	Rhinovirus infection		[1] 1 (0.6%)
	Sepsis		[1] 1 (0.6%)
Metabolism and nutrition disorders	#Total	[1] 1 (0.6%)	
	Poor feeding infant	[1] 1 (0.6%)	
Nervous system disorders	#Total		[1] 1 (0.6%)
	Febrile convulsion		[1] 1 (0.6%)
Respiratory, thoracic and mediastinal disorders	#Total	[1] 1 (0.6%)	
	Bronchial obstruction	[1] 1 (0.6%)	
Surgical and medical procedures	#Total	[1] 1 (0.6%)	
	Hospitalisation	[1] 1 (0.6%)	

Suspected Unexpected Serious Adverse Reaction

Table 4: Suspected Unexpected Serious Adverse Reaction by System Organ Class and Preferred term

System Organ Class	Preferred Term	Placebo	Amoxicillin
Infections and infestations	#Total	[1] 1 (0.6%)	[1] 1 (0.6%)
	Anal abscess	[1] 1 (0.6%)	
	Rhinovirus infection		[1] 1 (0.6%)