

# FDA - Adverse Event Reporting System (AERS)

## ISR Information Report for ISR #4693376-1

**ISR Information:**

ISR #: 4693376-1

Case #: 5820969

ISR Type: Expedited (15-Day)

FDA Rcvd. Date: 06/17/2005

Outcome(s): OT

Best Rep. ISR: Yes

eSub ISR: Yes

Initial or Follow-up ISR: Initial

Verbatim Follow-up #:

**Manufacturer Information:**

Sender Mfr.: NOVARTIS PHARMACEUTICALS CORP.

Mfr. Control #: PHBS2005GB08487

Mfr. Rcvd. Date: 06/08/2005

Primary Suspect (A)NDA/PLA #: 019667

**Patient Information:**

Patient ID: --

Age:

DoB:

Gender: Male

Weight:

Event Start Date:

**Reporter Information:**

 Reporter Name: 

Reporter Org.:

Reporter Street:

Reporter Zip:

Reporter Phone:

 Reporter City: 

Health Prof.: YES

Occupation: OTHER HEALTH PROFESSIONAL

Reporter State:

Reporter Country: UNITED KINGDOM

Reporter Name:

Reporter Org.:

Reporter Street:

Reporter Zip:

Reporter Phone:

Reporter City:

Health Prof.: YES

Occupation: OTHER HEALTH PROFESSIONAL

Reporter State:

Reporter Country:

Product(s)	Role	Dosage Text	Route	Lot #	Indication(s)	Therapy Start Date	Therapy End Date	Interval 1st Dose to Event:	DeC	ReC
NASOGASTRIC TUBE	C		UNKNOWN							
OCTREOTIDE ACETATE	P	2 ug/kg/hour	INTRAVENOUS		CHYLOTHORAX					
OCTREOTIDE ACETATE	S	4 ug/kg/hour	INTRAVENOUS							

**Reaction(s)**

ABDOMINAL DISTENSION

BLOOD LACTIC ACID INCREASED

C-REACTIVE PROTEIN INCREASED

ReC

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**Reaction(s)**

HAEMATOCHEZIA  
 NECROTISING COLITIS  
 NEUTROPENIA  
 PNEUMATOSIS INTESTINALIS  
 PYREXIA  
 THROMBOCYTOPENIA  
 VOMITING

ReC

**Relevant Laboratory Data:**

Test Date	Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail Y/N
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**Relevant Medical History**

Disease/Surgical Procedure	Start Date	End Date	Continuing	Comment
COARCTATION OF THE AORTA			UNKNOWN	
BRACHIAL PULSE DECREASED			UNKNOWN	
FEMORAL PULSE DECREASED			UNKNOWN	
TAKAYASU'S ARTERITIS			UNKNOWN	aortic arch hypoplasia
CATHETERISATION CARDIAC ANGIOGRAM			UNKNOWN	
CARDIAC FAILURE			UNKNOWN	
METABOLIC ACIDOSIS			UNKNOWN	
RESUSCITATION			UNKNOWN	cardiopulmonary resuscitation
STERNOTOMY			UNKNOWN	
CARDIAC PERFORATION SURGERY			UNKNOWN	
ISCHAEMIA			UNKNOWN	distal aortic ischemia
ABDOMINAL DISTENSION			UNKNOWN	
PLEURAL EFFUSION			UNKNOWN	
CHYLOTHORAX			UNKNOWN	

Medical History Product(s)	Start Date	End Date	Indication(s)	Reaction(s)
PROSTAGLANDIN E2				

**Event/Problem Narrative**

Initial literature report received on 08 Jun 2005: In a male infant an antenatal anomaly ultrasound scan had established a diagnosis of aortic coarctation. Diagnostic cardiac catheterization and angiography were performed following a clinical deterioration with onset of heart failure and metabolic acidosis. The procedure was complicated by cardiac tamponade due to hemopericardium caused by catheter perforation of the left atrial appendage. The baby required a brief period of cardiopulmonary resuscitation and emergency sternotomy with surgical repair of cardiac perforation. Subsequently an aortogram identified discrete preductal coarctation. The baby recovered well after these events requiring only low-dose inotropic support for transient low cardiac output and after 2 days was deemed stable enough to undergo surgical repair of aortic coarctation and ligation of the arterial duct. Following the operation, temporary abdominal distension was present without any other signs of necrotizing enterocolitis. During this time, the baby was nourished with total parenteral nutrition. On postoperative day 8, enteral feeding was commenced with expressed breast milk gradually increasing to 150 mL/kg/d over 3 days as parenteral nutrition was reduced proportionately. Following surgery, an echocardiogram demonstrated a good surgical repair with no evidence of residual obstruction to the baby's blood flow into the descending aorta. During attempts at ventilator weaning, a left hemidiaphragmatic palsy was diagnosed and surgical plication of the

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### Event/Problem Narrative

hemi-diaphragm undertaken. The baby subsequently made good progress toward tracheal extubation. Two weeks after the coarctation repair, a pleural effusion was diagnosed that required drainage. The fluid thus obtained contained concentrations of triglycerides and lymphocytes (2.5 mmol/L, and 2,600 cells/ $\mu$ L with 98 % of lymphocytes, respectively) consistent with diagnosis of chylothorax. This was initially treated by pleural drainage and a change to a formula containing medium chain triglycerides as the only source of fat. Intravenous infusion of octreotide (2 ug/kg later increased to 4 ug/kg) (manufacturer unknown) was also commenced following the failure of dietary regime to reduce volume of pleural drainage after 48 hrs. Within 72 hrs of starting treatment with octreotide, abdominal distension was noted together with fever, vomiting, and the passage of blood-stained stools. A plain abdominal radiograph revealed bowel wall pneumatosis. C-reactive protein and lactate concentrations were elevated together with neutropenia and thrombocytopenia. The findings were thought to be consistent with a diagnosis of necrotizing enterocolitis. Octreotide treatment and nasogastric feeding were discontinued, and conservative treatment with intravenous antibiotics and parenteral nutrition commenced. The baby responded well to this treatment, and abdominal surgical intervention was not required. Antibiotics were continued for 10 days and enteral feeding recommenced after 2 wks of parenteral nutrition. The baby was discharged at the age of 2 months at which time he was breast-fed, with no obvious abdominal sequelae. The authors concluded that the reduction in splanchnic blood flow induced by octreotide could have contributed to the development of necrotizing enterocolitis.

**Study Report?:** No

**Study Name:**

**Study Type:**

**Sponsor Study #:**

**Protocol #:**

**IND #:**

**Literature Text:** Pediatric Critical Care Medicine; Mohseni-Bod H, Macrae D, Slavik Z; 5(4); 2004; 356-357; Somatostatin analog (octreotide) in management of neonatal postoperative chylothorax: is it safe?