Steroid Trial WEB-ENTRY BARC WEB-ENTRY Form S11 Eligibility

A1. Site/Study ID #//						
SECTION B: INCLUSION CRITERIA – MAY BE COMPLETED PRIOR TO SURGERY (To be eligible, all answers must be Yes)						
B1. Surgical portoenterostomy for biliary atresia performed	within the previous 24 hour	s ZELB01SP V2(2) 1. No	2. Yes			
B2. Patient is enrolled in the BARC observational study (P003)		ZELB02PE V2(2) 1. No	2. Yes			
B3. Subject is at least 36 weeks post conception		ZELB03PC V2(2) 1. No	2. Yes			
B4. Subject's weight is at least 2 kg		ZELB04SW V2(2) 1. No	2. Yes			
B5. Informed written consent has been signed for P004		ZELB05WC V2(2) 1. No	2. Yes			
SECTION C: EXCLUSION CRITERIA (To be eligible, all a	inswers must be No)					
C1. Patient diagnosed with immunodeficiency	ZELC01PD V2(2)	1. No	2. Yes			
C2. Patient has hyperglycemia (glucose ≥200mg/dl)	ZELC02HY V2(2)	1. No	2. Yes			
C3. Patient has significant hypertension (≥112 mm Hg SBP	ZELC03SH V2(2)	1. No	2. Yes			
C4. Patient known to have sensitivity to corticosteroids	ZELC04CO V2(2)	1. No	2. Yes			
C5. Patient has bacteremia or a clinically relevant tissue info	ection ZELC05TI V2(2)	1. No	2. Yes			
C6. Patient known to have congenital infection or disease with herpes simplex virus, toxoplasmosis, or cytomegalovirus inclusion disease of the liver ZELCO6CI V2(2) 1. No 2. Yes						
C7. Mother known to have immunodeficiency virus (HIV) inf	fection ZELC07VI V2(2)	1. No	2. Yes			
C8. Mother known to have Hepatitis B or Hepatitis C infection	on ZELC08HB V2(2)	1. No	2. Yes			
C9. Patient known to have clinical condition that would contraindicate the use of corticosteroids ZELC09CC V2(2) ₁ . No 2. Yes						
C10. Patient has serum indirect (unconjugated) bilirubin ≥ 5 mg/dL for infants under 4 weeks of age or ≥ 7 mg/dL for infants between 4 and 8 weeks of age ZELC10UB V2(2) 1. No 2. Yes						
C11. Patient has other severe concurrent illness, such as neurological, cardiovascular, pulmonary, metabolic, endocrine or renal disorders that would interfere with the conduct of the study ZELC11Cl V2(2)1. No 2. Yes						
C12. Has the subject received a vaccination for rotavirus in the	he last 5 days? ZELC12	2CI V2(2)	1. No 2. Yes			
SECTION D: POST-SURGICAL CONDITIONS						
D1. Hypertension (SBP ≥112) ZELD01HY V2((2)	No Ye	s→ INELIGIBLE			
D2. Hyperglycemia (glucose ≥200mg/dl) ZELD02GL V2(2) 1.	No 2. Ye	s→ INELIGIBLE			
D3. Hypokalemia (potassium level <3.0 meg/L) ZELD03Pl	_ V2(2)	No 2. Ye	s→ Complete form S11D			

Steroid Trial	WEB-ENTRY	BARC	WEB-ENTRY	Form S11 Eligibility

A1. Site/Study ID #//	-				
D4. Impaired wound healing	ZELD04IW V2(2)	1. No	2. Yes→ INELIGIBLE		
D5. GI bleeding reported or found	ZELD05GI V2(2)	1. No	2. Yes→ Complete form S11F		
D6. Pancreatitis diagnosed	ZELD06PD V2(2)	1. No	2. Yes→ Complete form S11G		
D7. Severe irritability present	ZELD07SI V2(2)	1. No	2. Yes		
D8. Vaccine preventable infection reported or	found ZELD08VP V2(2)	1. No	2. Yes		
D9. Cataracts reported or found	ZELD09CR V2(2)	1. No	2. Yes		
SECTION E: SUMMARY					
E1. Patient is: ZELE01PI V2(2) 1. Eligible 2. Eligible by exemption		3. Not eligible → END			
E2. Patient randomization number (from pharmacy) ZELE02RN V2(5)					

Investigator Signature: ZELINSIG V2(2)

Date: ZELSIGMM V2(2)/ ZELSIGDD V2(2)/ ZELSIGYY V2(4)/ ZELSIGDT

Month

Day

Year

ZELCMMNT V2(800) Comment