ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 25, 2019

ClinicalTrials.gov ID: NCT00850993

Study Identification

Unique Protocol ID:	64,185-202
Brief Title:	A Safety and Efficacy Trial of Stannsoporfin in Neonates With Hyperbilirubinemia
Official Title:	A Phase 2b, Multicenter, Single-dose, Blinded, Randomized, Placebo-controlled, Dose-escalation, Safety and Efficacy Trial of Stannsoporfin in Neonates With Hyperbilirubinemia
Secondary IDs:	2009-017434-45 [EudraCT Number]

Study Status

Record Verification:	August 2014
Overall Status:	Terminated [To redefine study population]
Study Start:	August 2008 []
Primary Completion:	June 2011 [Actual]
Study Completion:	May 2012 [Actual]

Sponsor/Collaborators

Sponsor:	InfaCare Pharmaceuticals Corporation, a Mallinckrodt Company
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 64,185 Serial Number: 137 Has Expanded Access: No
Human Subjects Review:	Board Status: Approved
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary: It is a normal process in the human body for red blood cells to die, which makes bilirubin.

Bilirubin is cleared away through the liver.

Some babies are born with livers that don't work well enough yet, or their red blood cells are dying too fast, so the baby looks yellow (jaundice).

This means there is too much bilirubin in the body. It can be dangerous if a baby's bilirubin gets too high.

Phototherapy is what they call the lights they shine on newborn babies to help the liver get rid of bilirubin.

This study tests an experimental drug to see if it can reduce how much bilirubin is being made in the first place.

Detailed Description: The purpose of this study is to determine if an experimental drug, stannsoporfin, is safe and effective in the treatment of hyperbilirubinemia in hemolyzing neonates.

Conditions

Conditions:	Hyperbilirubinemia, Neonatal
Keywords:	Hemolysis

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment Sequential experimental cohorts are run in parallel with placebo controls.
Number of Arms:	4
Masking:	Double (Participant, Investigator) Clinical personnel at the site (including investigator, study coordinator and central cardiologist) were blinded to treatment group. The research pharmacy and the health care provider responsible for giving the injection to patients knew what the treatment was (they were not blinded).
Allocation:	Randomized
Enrollment:	58 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Cohort 1: Stannsoporfin 1.5 mg/kg Participants receive a single dose of 1.5 mg/kg by intramuscular (IM) injection, along with PhotoTherapy (PT) if and when needed.	Drug: Stannsoporfin Stannsoporfin administered as a single IM injection Other Names: • Experimental product PhotoTherapy (as needed) PT standard care administered as needed, based on bilirubin levels throughout the treatment period Other Names: • PT
Experimental: Cohort 2: Stannsoporfin 3.0 mg/kg Participants receive a single dose of 3.0 mg/kg by intramuscular (IM) injection, along with PT if and when needed.	Drug: Stannsoporfin Stannsoporfin administered as a single IM injection Other Names: • Experimental product PhotoTherapy (as needed) PT standard care administered as needed, based on bilirubin levels throughout the treatment period Other Names: • PT
Experimental: Cohort 3: Stannsoporfin 4.5 mg/kg Participants receive a single dose of 4.5 mg/kg by intramuscular (IM) injection, along with PT if and when needed.	Drug: Stannsoporfin Stannsoporfin administered as a single IM injection Other Names: • Experimental product

Arms	Assigned Interventions
	PhotoTherapy (as needed) PT standard care administered as needed, based on bilirubin levels throughout the treatment period Other Names: • PT
Placebo Comparator: Cohort 4: Placebo Participants receive a single dose of placebo (sterile saline solution) by IM injection, along with PT if and when needed.	Placebo Placebo (sterile saline solution) administered as a single IM injection Other Names: • Saline PhotoTherapy (as needed) PT standard care administered as needed, based on bilirubin levels throughout the treatment period Other Names: • PT

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 1 Minutes

Maximum Age: 48 Hours

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

Babies may only participate if they meet all the following criteria:

- Is a term or late preterm baby
- Is at risk for protocol-defined hemolytic disease
- Weighs at least 2500 g (5.5 lbs)
- Has total serum bilirubin (TSB) a specified amount lower than the phototherapy threshold for the age
- Has parents/guardians who are willing to follow light precautions and sign informed consent

Exclusion Criteria:

The following criteria will make a baby not eligible to participate:

- Needs medications that may prolong the QT interval
- Has family history or risk factors for Long QT Syndrome, Sudden Infant Death Syndrome, or Porphyrias
- Has an Apgar score of 6 or below at age 5 minutes
- Has abnormalities or infections (in mother or child) that per protocol or in the opinion of the investigator may compromise the safety and well-being of the baby or analysis of study results

Contacts/Locations

Central Contact Person:

Central Contact Backup:

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IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	Fifty-eight (58) babies were enrolled before the trial was prematurely terminated due to cancellation.
Pre-assignment Details	Because the cohorts were run sequentially, and the trial was cancelled before they were all enrolled, Cohort 3 enrolled only 8 compared to 15 in Cohort 4.

Reporting Groups

	Description
Cohort 1: Stannsoporfin 1.5 mg/kg	1.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 2: Stannsoporfin 3.0 mg/kg	3.0 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 3: Stannsoporfin 4.5 mg/kg	4.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 4: Placebo Control	Placebo control was sterile saline solution (with phototherapy as needed)

Overall Study

	Cohort 1: Stannsoporfin 1.5 mg/kg	Cohort 2: Stannsoporfin 3.0 mg/kg	Cohort 3: Stannsoporfin 4.5 mg/kg	Cohort 4: Placebo Control
Started	17	18	8	15
Safety	17	18	8	15
Intent-to-treat	17	18	8	15
Received Phototherapy	3	6	2	8
Per Protocol	10	13	5	13
Completed	16	18	8	14
Not Completed	1	0	0	1
Parent/ Guardian Voluntarily Withdrew	1	0	0	1

Baseline Characteristics

Baseline Analysis Population Description
Intention-to-treat

Reporting Groups

	Description
Cohort 1: Stannsoporfin 1.5 mg/kg	1.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 2: Stannsoporfin 3.0 mg/kg	3.0 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 3: Stannsoporfin 4.5 mg/kg	4.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 4: Placebo Control	Placebo control was sterile saline solution (with phototherapy as needed)

Baseline Measures

		Cohort 1: Stannsoporfin 1.5 mg/kg	Cohort 2: Stannsoporfin 3.0 mg/kg	Cohort 3: Stannsoporfin 4.5 mg/kg	Cohort 4: Placebo Control	Total
Overall Number of Participants		17	18	8	15	58
Age, Customized [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	18 participants	8 participants	15 participants	58 participants
35 through 37 Weeks		2 11.76%	0 0%	1 12.5%	3 20%	6 10.34%
38 Weeks and Above		15 88.24%	18 100%	7 87.5%	12 80%	52 89.66%
		[1] Measure Description: Gestational Age, Categorical				
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	18 participants	8 participants	15 participants	58 participants
	Female	10 58.82%	6 33.33%	6 75%	7 46.67%	29 50%
	Male	7 41.18%	12 66.67%	2 25%	8 53.33%	29 50%

		Cohort 1: Stannsoporfin 1.5 mg/kg	Cohort 2: Stannsoporfin 3.0 mg/kg	Cohort 3: Stannsoporfin 4.5 mg/kg	Cohort 4: Placebo Control	Total
Ethnicity (NIH/ OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	18 participants	8 participants	15 participants	58 participants
	Hispanic or Latino	5 29.41%	6 33.33%	6 75%	4 26.67%	21 36.21%
	Not Hispanic or Latino	12 70.59%	12 66.67%	2 25%	11 73.33%	37 63.79%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%	0 0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	18 participants	8 participants	15 participants	58 participants
	American Indian or Alaska Native	0 0%	1 5.56%	0 0%	0 0%	1 1.72%
	Asian	0 0%	2 11.11%	0 0%	1 6.67%	3 5.17%
	Native Hawaiian or Other Pacific Islander	4 23.53%	3 16.67%	0 0%	4 26.67%	11 18.97%
	Black or African American	5 29.41%	2 11.11%	0 0%	2 13.33%	9 15.52%
	White	7 41.18%	7 38.89%	6 75%	3 20%	23 39.66%
	More than one race	0 0%	0 0%	0 0%	0 0%	0 0%
	Unknown or Not Reported	1 5.88%	3 16.67%	2 25%	5 33.33%	11 18.97%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change in Adjusted Total Serum Bilirubin (TSB) From Baseline to 48 Hours After Treatment.
Measure Description	The adjusted TSB is a calculation of the percentage difference of the TSB level from the age-specific threshold for PT initiation per the American Academy of Pediatrics (AAP) Guidelines, ie, an indication of the distance below the PT threshold at the time [(TSB - PT threshold/PT threshold) x 100%).
Time Frame	Baseline, 48 hours

Analysis Population Description

Intent-to-treat population (ITT)

Reporting Groups

	Description
Cohort 1: Stannsoporfin 1.5 mg/kg	1.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 2: Stannsoporfin 3.0 mg/kg	3.0 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 3: Stannsoporfin 4.5 mg/kg	4.5 mg/kg stannsoporfin (with phototherapy as needed)
Placebo Control	Sterile saline solution (with phototherapy as needed)

Measured Values

	Cohort 1: Stannsoporfin 1.5 mg/kg	Cohort 2: Stannsoporfin 3.0 mg/kg	Cohort 3: Stannsoporfin 4.5 mg/kg	Placebo Control
Overall Number of Participants Analyzed	17	18	8	15
Change in Adjusted Total Serum Bilirubin (TSB) From Baseline to 48 Hours After Treatment. Median (Full Range) Unit of measure: percentage difference from PT threshold	-12.30 (-55.7 to 0.3)	-9.05 (-54.8 to 12.0)	-19.95 (-59.0 to -5.0)	-5.7 (-42.1 to 22.2)

Statistical Analysis 1 for Change in Adjusted Total Serum Bilirubin (TSB) From Baseline to 48 Hours After Treatment.

Statistical Analysis Overview	Comparison Group Selection	Cohort 1: Stannsoporfin 1.5 mg/kg, Placebo Control
	Comments	Last Observation Carry Forward (LOCF) is used to impute missing post-baseline TSB. Least-squares means are from an ANCOVA model for adjusted TSB with treatment and gestational age as fixed effects and baseline adjusted TSB as a covariate. TSB is calculated as [(TSB - Phototherapy(PT) threshold)/ PT threshold] X 100%.

	Type of Statistical Test	Other
	Comments	Pairwise comparison for each Stannsoporfin treatment group versus placebo.

Statistical Test of Hypothesis	P-Value	=0.040
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-13.45
	Confidence Interval	(2-Sided) 95% -26.27 to -0.62
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change in Adjusted Total Serum Bilirubin (TSB) From Baseline to 48 Hours After Treatment.

Statistical Analysis Overview	Comparison Group Selection	Cohort 2: Stannsoporfin 3.0 mg/kg, Placebo Control
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	=0.117
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-10.02
	Confidence Interval	(2-Sided) 95% -22.61 to 2.58
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change in Adjusted Total Serum Bilirubin (TSB) From Baseline to 48 Hours After Treatment.

Statistical Analysis Overview	Comparison Group Selection	Cohort 3: Stannsoporfin 4.5 mg/kg, Placebo Control
	Comments	[Not specified]

	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	=0.057
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-14.93
	Confidence Interval	(2-Sided) 95% -30.31 to 0.44
	Estimation Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Change From Baseline in Total Serum Bilirubin (TSB) at 48 Hours (ITT Population
Measure Description	Total bilirubin in blood serum was measured at baseline and at 48 hours after the shot. Change from baseline is calculated by subtracting the amount at baseline from the amount at 48 hours. Lower numbers are better.
Time Frame	Baseline, 48 hrs

Analysis Population Description
Intention-to-treat

Reporting Groups

	Description
Cohort 1: Stannsoporfin 1.5 mg/kg	1.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 2: Stannsoporfin 3.0 mg/kg	3.0 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 3: Stannsoporfin 4.5 mg/kg	4.5 mg/kg stannsoporfin (with phototherapy as needed)
Placebo Control	Sterile saline solution (with phototherapy as needed)

Measured Values

	Cohort 1: Stannsoporfin 1.5 mg/kg	Cohort 2: Stannsoporfin 3.0 mg/kg	Cohort 3: Stannsoporfin 4.5 mg/kg	Placebo Control
Overall Number of Participants Analyzed	17	18	8	15
Change From Baseline in Total Serum Bilirubin (TSB) at 48 Hours (ITT Population Median (Full Range) Unit of measure: mg/dL				
at Baseline	7.80 (4.3 to 12.0)	8.45 (5.5 to 10.4)	9.35 (6.4 to 12.8)	8.00 (4.6 to 11.9)
at 48 hours	10.90 (3.3 to 13.5)	11.65 (4.2 to 14.1)	10.35 (5.6 to 13.4)	11.90 (8.1 to 15.8)
Change from Baseline at 48 hours	2.70 (-4.5 to 5.2)	2.94 (-3.4 to 6.2)	1.45 (-3.4 to 3.6)	3.70 (-0.2 to 8.7)

Statistical Analysis 1 for Change From Baseline in Total Serum Bilirubin (TSB) at 48 Hours (ITT Population

Statistical Analysis Overview	Comparison Group Selection	Cohort 1: Stannsoporfin 1.5 mg/kg, Placebo Control
	Comments	Last Observation Carry Forward (LOCF) is used to impute missing post-baseline TSB. Analysis of covariance (ANCOVA) is conducted for TSB including treatment and gestational age as fixed effects and baseline TSB as a covariate. Least-squares means (LS means) and standard errors (SEM) are estimated for each treatment group and placebo. LS mean difference, 95% Confidence Interval, and p-value are estimated based on LS mean difference between each stannsoporfin group and placebo.
	Type of Statistical Test	Other
	Comments	Pairwise comparison for Change from Baseline at 48 hours (Row 3) for Stannsoporfin treatment group versus placebo

Statistical Test of Hypothesis	P-Value	=0.061
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-1.81
	Confidence Interval	(2-Sided) 95% -3.71 to 0.09

	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in Total Serum Bilirubin (TSB) at 48 Hours (ITT Population

Statistical Analysis Overview	Comparison Group Selection	Cohort 2: Stannsoporfin 3.0 mg/kg, Placebo Control
	Comments	Last Observation Carry Forward (LOCF) is used to impute missing post-baseline TSB. Analysis of covariance (ANCOVA) is conducted for TSB including treatment and gestational age as fixed effects and baseline TSB as a covariate. Least-squares means (LS means) and standard errors (SEM) are estimated for each treatment group and placebo. LS mean difference, 95% Confidence Interval, and p-value are estimated based on LS mean difference between each stannsoporfin group and placebo.
	Type of Statistical Test	Other
	Comments	Pairwise comparison for Change from Baseline at 48 hours (Row 3) for Stannsoporfin treatment group versus placebo

Statistical Test of Hypothesis	P-Value	=0.163
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-1.34
	Confidence Interval	(2-Sided) 95% -3.24 to 0.56
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in Total Serum Bilirubin (TSB) at 48 Hours (ITT Population

Statistical Analysis Overview	Comparison Group Selection	Cohort 3: Stannsoporfin 4.5 mg/kg, Placebo Control
	Comments	Last Observation Carry Forward (LOCF) is used to impute missing post-baseline TSB. Analysis of covariance (ANCOVA) is conducted for TSB including treatment and gestational age as fixed effects and baseline TSB as a covariate. Least-squares means (LS means) and standard errors (SEM) are estimated for each treatment group and placebo. LS mean difference, 95% Confidence Interval, and p-value are estimated based on LS mean difference between each stannsoporfin group and placebo.
	Type of Statistical Test	Other
	Comments	Pairwise comparison for Change from Baseline at 48 hours (Row 3) for Stannsoporfin treatment group versus placebo

Statistical Test of Hypothesis	P-Value	=0.028
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-2.63
	Confidence Interval	(2-Sided) 95% -4.97 to -0.3
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	30 days
Adverse Event Reporting Description	All adverse events were collected by the investigator except jaundice and hyperbilirubinemia after the first amendment.

Reporting Groups

	Description
Cohort 1: Stannsoporfin 1.5 mg/kg	1.5 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 2: Stannsoporfin 3.0 mg/kg	3.0 mg/kg stannsoporfin (with phototherapy as needed)
Cohort 3: Stannsoporfin 4.5 mg/kg	4.5 mg/kg stannsoporfin (with phototherapy as needed)
Placebo Control	Sterile saline solution (with phototherapy as needed)

All-Cause Mortality

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total All-Cause Mortality	0/17 (0%)		0/18 (0%)		0/8 (0%)		0/15 (0%)	

Serious Adverse Events

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	0/17 (0%)		1/18 (5.56%)		1/8 (12.5%)		2/15 (13.33%)	
Blood and lymphatic system disorders								
Anemia [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Hepatobiliary disorders								
hyperbilirubinaemia [A] †	0/17 (0%)	0	0/18 (0%)	0	0/8 (0%)	0	2/15 (13.33%)	2
Infections and infestations								
meningitis [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	8/17 (47.06%)		10/18 (55.56%)		3/8 (37.5%)		5/15 (33.33%)	
Blood and lymphatic system disorders								
Anaemia [A] †	0/17 (0%)	0	1/18 (5.56%)	1	2/8 (25%)	2	0/15 (0%)	0
Leukocytosis [A] †	1/17 (5.88%)	1	2/18 (11.11%)	2	0/8 (0%)	0	0/15 (0%)	0
Thrombocytopenia [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Cardiac disorders								
Bradycardia [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0
Gastrointestinal disorders								
Hyperbilirubinaemia [A] †	2/17 (11.76%)	2	1/18 (5.56%)	1	0/8 (0%)	0	2/15 (13.33%)	2
Jaundice [A] †	5/17 (29.41%)	5	0/18 (0%)	0	0/8 (0%)	0	1/15 (6.67%)	1
Umbilical hernia [A] †	0/17 (0%)	0	0/18 (0%)	0	0/8 (0%)	0	1/15 (6.67%)	1
Vomiting [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Infections and infestations								
Anal abscess [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Meningitis [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0
Oral candidiasis [A] †	0/17 (0%)	0	0/18 (0%)	0	0/8 (0%)	0	2/15 (13.33%)	2
Injury, poisoning and procedural complications								
Contusion [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Investigations								
Blood glucose decreased [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Blood sodium increased [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
C-reactive protein increased [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Carbon dioxide decreased [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Haemoglobin increased [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
Haemangioma [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Nervous system disorders								
Depressed level of consciousness [A] †	0/17 (0%)	0	0/18 (0%)	0	1/8 (12.5%)	1	0/15 (0%)	0
Skin and subcutaneous tissue disorders								
Acne infantile [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Dermatitis contact [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Dermatitis diaper [A] †	2/17 (11.76%)	2	1/18 (5.56%)	1	0/8 (0%)	0	1/15 (6.67%)	1
Erythema [A] †	0/17 (0%)	0	1/18 (5.56%)	1	1/8 (12.5%)	1	0/15 (0%)	0
Erythema toxicum neonatorum [A] †	0/17 (0%)	0	3/18 (16.67%)	3	0/8 (0%)	0	0/15 (0%)	0
Rash [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Rash neonatal [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0
Rash papular [A] †	0/17 (0%)	0	0/18 (0%)	0	0/8 (0%)	0	1/15 (6.67%)	1
Seborrhoeic dermatitis [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0

	Cohort 1: Stannsoporfin 1.5 mg/kg		Cohort 2: Stannsoporfin 3.0 mg/kg		Cohort 3: Stannsoporfin 4.5 mg/kg		Placebo Control	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Skin exfoliation [A] †	1/17 (5.88%)	1	0/18 (0%)	0	0/8 (0%)	0	0/15 (0%)	0
Vascular disorders								
Flushing [A] †	0/17 (0%)	0	1/18 (5.56%)	1	0/8 (0%)	0	0/15 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

It should be noted that the study was discontinued before enrollment of the full 4.5 mg/kg cohort,and therefore, the stannsoporfin 4.5 mg/kg treatment group included 8 patients and the placebo group included 15 patients.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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