

Study Title: Rand, DB, Plac-cont trial of North american ginseng extract to prev resp inf and red antibiotic use

Patient Initial/PID# _____ Visit Date _____ Site Name _____

Toxicity Assessment Sheet (TAS)- Circle the appropriate toxicity grade below

Confusion			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Transient confusion, disorientation, or attention deficit	Grade2 Confusion, disorientation, or attention deficit interfering with function, but not interfering with ADL	Grade3 Confusion or delirium interfering with ADL	Grade4 Harmful to others or self; hospitalization indicated	Grade 5 (death)		
Constitutional Symptoms - Hyperactivity			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild	Grade2 Moderate	Grade3 Severe	Grade4 Life-threatening; disabling	Grade 5 (death)		
Diarrhea (without colostomy)			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Increase of <4 stools/day over baseline; mild increase in ostomy output compared to baseline	Grade2 Increase of 4-6 stools per day over baseline; IV fluids indicated <24 hours; moderate increase in ostomy output compared to baseline; not interfering with ADL	Grade3 Increase of >=7 stools/day over baseline; incontinence; IV fluids >=24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL	Grade4 Life-threatening consequences (e.g. hemodynamic collapse)	Grade 5 (death)		
Dizziness			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 With head movements or nystagmus only; not interfering with function	Grade2 Interfering with function, but not interfering with ADL	Grade3 Interfering with ADL	Grade4 Disabling	Grade 5 (death)		
Glucose Serum High - Hyperglycemia			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 > ULN - 160 MG/DL > ULN - 8.9 mmol/L	Grade2 > 160 - 250 mg/dl > 8.9 - 13.9 mmol/L	Grade3 > 250 - 500 mg/dL > 13.9 - 27.8 mmol/L	Grade4 > 500 mg/dL > 27.8 mmol/L or acidosis	Grade 5 (death)		
Headache			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild pain not interfering with function	Grade2 Moderate pain; pain or analgesics interfering with function, but not interfering with ADL	Grade3 Severe pain; pain or analgesics severely interfering with ADL	Grade4 Disabling	Grade 5 (death)		
Heartburn			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild	Grade2 Moderate	Grade3 Severe	Grade 5 (death)			
Hemorrhage, Nose (Epistaxis)			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild, Intervention not indicated	Grade2 Symptomatic and medical intervention indicated	Grade3 Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e., hemostasis of bleeding site)	Grade4 Life-threatening consequences; major urgent intervention indicated	Grade 5 (death)		
Hypertension			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Asymptomatic, transient (<24 hrs) increase by >20 mmHg (diastolic) or to > 150/100 if previously WNL; intervention not indicated	Grade2 Recurrent or persistent (>=24 hrs) or symptomatic increase by > 20 mmHg (diastolic) or to > 150/100 if previously WNL; monotherapy may be indicated	Grade3 Requiring more than one drug or more intensive therapy than previously	Grade4 Life-threatening consequences (e.g. hypertensive crisis)	Grade 5 (death)		
Hypotension			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Changes, intervention not indicated	Grade2 Brief (<24 hrs) fluid replacement or other therapy; no physiologic consequences	Grade3 Sustained (>=24hrs) therapy, resolves without persisting physiologic consequences	Grade4 Shock (e.g., acidemia; impairment of vital organ function)	Grade 5 (death)		
Insomnia			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Occasional difficulty sleeping, not interfering with function	Grade2 Difficulty sleeping, interfering with function but not interfering with ADL	Grade3 Frequent difficulty sleeping, interfering with ADL	Grade4 Disabling	Grade 5 (death)		
Nausea			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Loss of appetite without alteration in eating habits	Grade2 Oral intake decreased without significant weight loss, dehydration or malnutrition; IV fluids indicated <24 hours	Grade3 Inadequate oral caloric or fluid intake; IV fluids, tube feedings, or TPN indicated > or equal to 24 hours	Grade4 Life-threatening consequences	Grade 5 (death)		
Neurology - Other - Nervousness			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild	Grade2 Moderate	Grade3 Severe	Grade4 Life-threatening; disabling	Grade 5 (death)		
Pain - Joint Pain			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Mild pain not interfering with function	Grade2 Moderate pain; pain or analgesics interfering with function, but not interfering with ADL	Grade3 Severe pain; pain or analgesics severely interfering with ADL	Grade4 Disabling	Grade 5 (death)		
Rash/desquamation			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 macular or papular eruption or erythema without associated symptoms	Grade2 macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Grade3 symptomatic generalized erythroderma or macular papular or vesicular eruption or desquamation covering >50% of body surface area	Grade4 generalized exfoliative dermatitis or ulcerative dermatitis	Grade 5 (death)		

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Somnolence			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None		Grade2 Somnolence or sedation interfering with function, but not interfering with ADL	Grade3 Obtundation or stupor; difficult to arouse; interfering with ADL	Grade4 Coma	Grade 5 (death)		
Urinary Frequency /Urgency - Pollakiuria			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 Increase in frequency or nocturia up to 2 x normal; enuresis	Grade2 Increase >2 x normal but <hourly	Grade3 >= 1 x/hr; urgency; catheter indicated	Grade 5 (death)			
Vomiting			For grade 3,4 &5: *Drug related? 1 2 3 4 5 (circle #)				
Grade0 None	Grade1 1 episode in 24 hrs over pretreatment	Grade2 2-5 episodes in 24 hrs over pretreatment	Grade3 6-10 episodes in 24 hrs over pretreatment; or need for IV fluids	Grade4 requiring parenteral nutrition; or physiologic consequences requiring intensive care;	Grade 5 (death) hemodynamic collapse		