

CO
Re

Protocol Elig & Rx Summary

Printable
Version

Chairman: Szklaruk, Janio

Manager:

Protocol
Number: 2011-0279Title: Utility of Post- Gd-EOB-DTPA MR Imaging in Prediction of
Compensatory Hypertrophy of the Liver Following Portal Vein
Embolization (PVE)On Core
Flag: Reg & Cont Rev & Demog & AE & Prot SummaryMulticenter
Study:
MDACC as
Primary Site:
Multicenter
Total:

N

0

IRB Approval Date	External IRB Effective Date	Activation Date	CNPE Date	Termination Date	Withdrawn Date	Patients Registered	Maximum Patients
SEP 15, 11		DEC 06, 11	OCT 01, 15			18	20

Registration Eligibility Criteria		Active	Inactive	Yes	No	Not Assd	Not App
1	Patients who are scheduled for a pre-operative MR evaluation of the liver for liver metastases or primary liver tumors.	DEC 06, 11	APR 16, 13	X			
2	The MR examination includes the use of Gd-EOB-DTPA as the contrast of choice.	DEC 06, 11		X			
3	Patients that are surgical candidates and are scheduled for a PVE procedure prior to surgery.	DEC 06, 11		X			
4	Patients who had a pre-PVE and will have a post-PVE imaging study and calculated segmental liver volumes.	DEC 06, 11		X			
5	Patients who are under 18 years of age.	DEC 06, 11			X		
6	Patients who are contraindicated for MR imaging	DEC 06, 11			X		
7	Patients who are pregnant	DEC 06, 11			X		X
8	Patients who are scheduled for a pre-operative MR or CT evaluation of the liver for liver metastases or primary liver tumors.	APR 16, 13	AUG 07, 14	X			
9					X		

	Patients with cirrhosis. The cirrhotic livers may be problematic as their maximum enhancement may not reach at 20 minutes.	APR 16, 13					
10	Patients who have had within 30 days or are scheduled for a pre-operative MR or CT evaluation of the liver for liver metastases or primary liver tumors.	AUG 07, 14		X			

--

Treatment Regimens	Treatment Steps	Max CrossOver	Accrual	Allowed
--------------------	-----------------	---------------	---------	---------

--

Treatment Strata	Step	Permissible Regimens	Max Patients	Current Patients	User Assignable Rx
------------------	------	----------------------	--------------	------------------	--------------------