

N06CA: The Use of Topical Baclofen, amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study

This study is open to MCR patients only. If the patient and physician want to continue with the active gel, or if on the placebo, begin the active gel, call (507/248-4130) or fax (507/284-0885) a completed continuation phase eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

Has the patient ever been on a prior study entered through this Registration Office? ____ Yes ____ No

If yes: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) __ __/__ __/__ __ __ __
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location _____
NCCTG treating physician/allied health professional _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) __ __/__ __/__ __ __ __

Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Registration Check

Yes No

The double-blind phase of the study must be completed prior to the treatment code being broken; that is, after the treating site has received the completed patient questionnaire booklet.	____	____
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All responses in above section must be "Yes"

Assigned Treatment

_____ Amitriptyline HCL/baclofen/ketamine gel

Person registering _____ Signature
Registration Office Specialist _____ initials

Physician _____ Signature
M D Y