

MC-5A for painful chemotherapy-induced peripheral neuropathy

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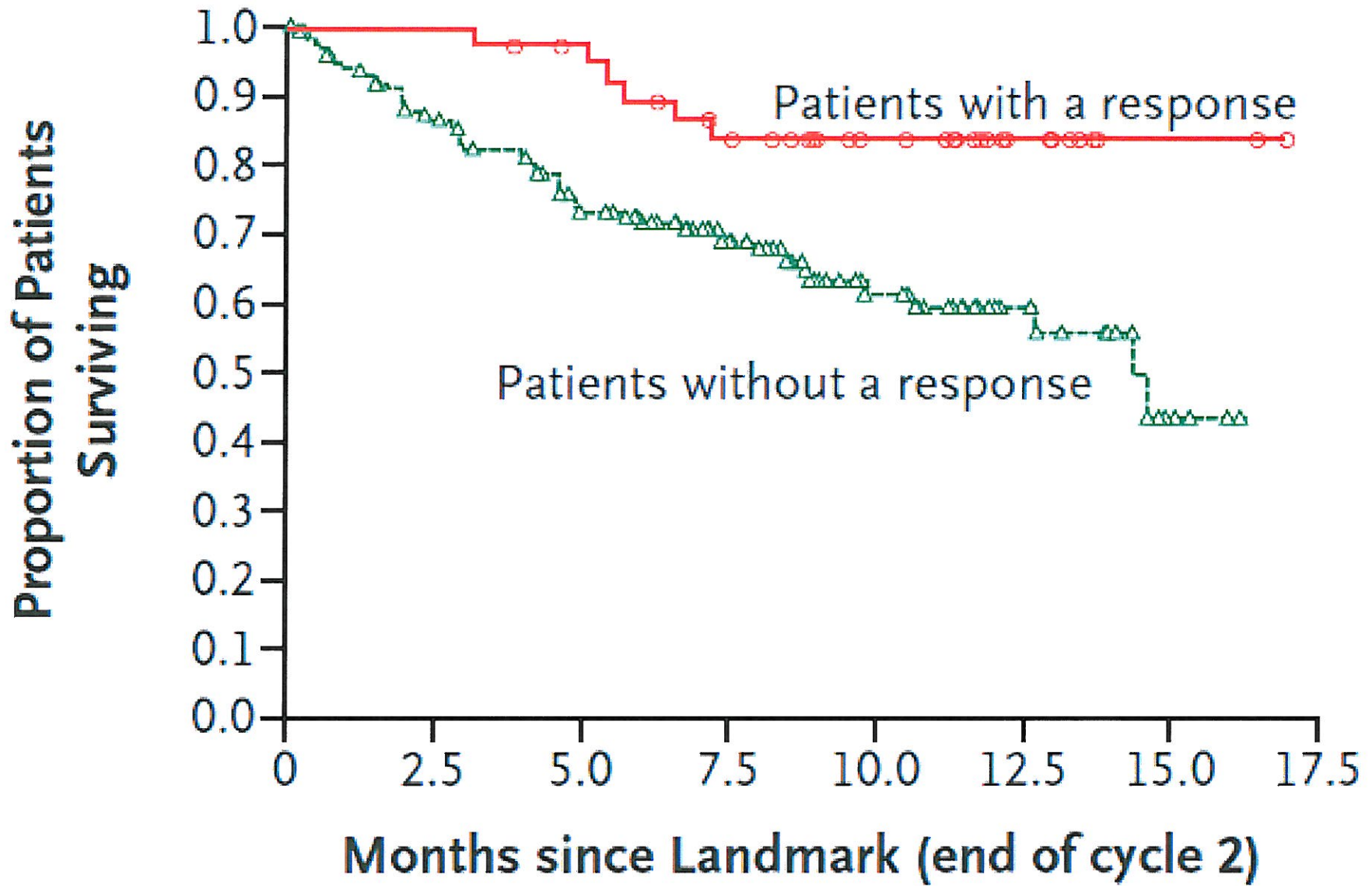
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**SCHOOL OF MEDICINE
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overview

- Background on chemotherapy-induced peripheral neuropathy (CIPN)
- CIPN protocol details
- CIPN research agenda and aims

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Chemotherapy Regimen: FOLFOX4 Based

Decision: No Additional Therapy



■ 48 out of 100 people are alive in 5 years.

■ 52 out of 100 people die because of cancer.

■ Less than 1 out of 100 people die of other causes.

Decision: Chemotherapy



■ 48 out of 100 people are alive in 5 years. Plus...

■ 21 out of 100 people are alive because of therapy.

■ 30 out of 100 people die because of cancer.

■ 1 out of 100 people die of other causes.

CIPN symptoms

- Symmetrical, progressive, length-dependent, sensory-dominant neuropathy
- Painful and painless
- Functional impairment

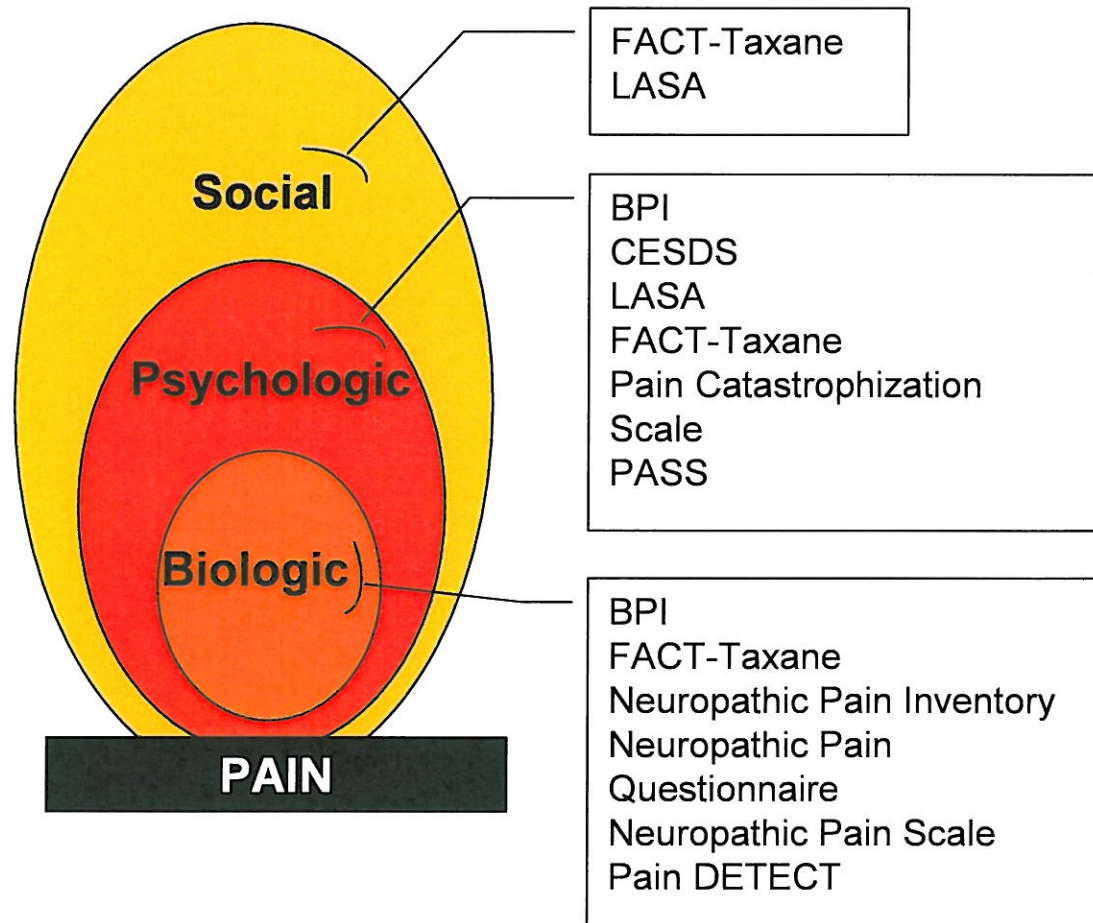
barriers

Adverse Event	Short Name	Grade				
		1	2	3	4	5
Pain – <i>Select</i> . ' <i>Select</i> ' AEs appear at the end of the CATEGORY.	Pain – <i>Select</i>	Mild pain not interfering with function	Moderate pain; pain or analgesics interfering with function, but not interfering with ADL	Severe pain; pain or analgesics severely interfering with ADL	Disabling	—
Neuropathy: sensory	Neuropathy-sensory	Asymptomatic; loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Sensory alteration or paresthesia (including tingling), interfering with function, but not interfering with ADL	Sensory alteration or paresthesia interfering with ADL	Disabling	Death

REMARK: Cranial nerve sensory neuropathy is graded as Neuropathy: cranial – *Select*.

measurement

- Neuropathic Pain Consortium
Quantitative Neurosensory Testing
(QSPT) Protocol
 - Questionnaires:
 - psychological well-being, QOL, function
 - pain and neuropathy assays

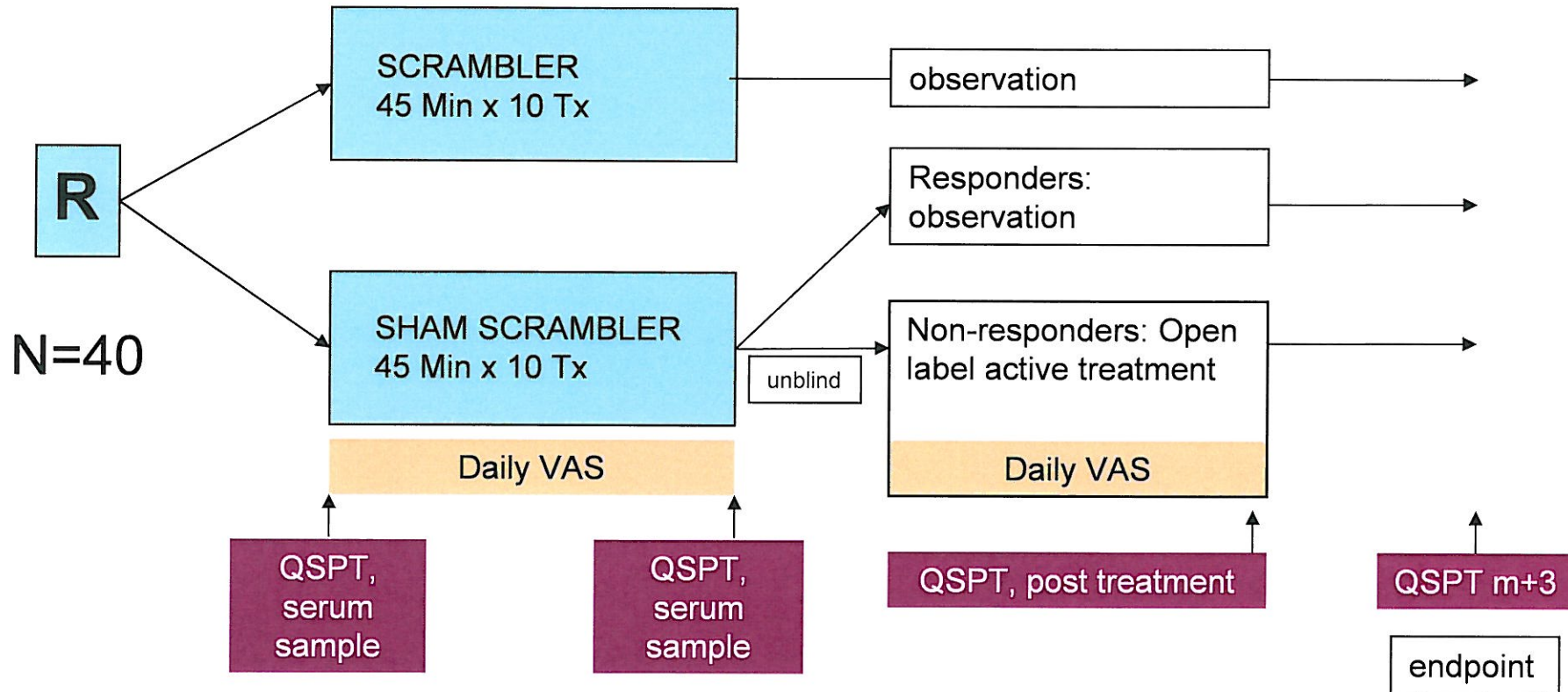




sham

- symmetrical, biphasic square waveform with similar cutaneous tingling sensation.
- The placebo waveform generated by a custom-built circuitry independent of the MC-5A circuitry so the original waveform circuitry is not modified.
- MC-5A front panel displays appear the same in both modes.
- An arbitrary waveform generator and current-limited amplifier allow the current level and sensation to be modulated.

protocol details



next steps

- R01, replicate randomized phase III multi-center study
- R01 with broader entry criteria in neuropathic pain
- Other pain syndromes e.g. sham-controlled prevention of post-thoracotomy pain