

Evaluation of Wire Electrodes to Activate the Expiratory Muscles to Restore
Cough / Sub-study to Spinal Cord Stimulation to Restore Cough

IRB08-00269/IRB98-00091

Title of Document: Study Protocol

Sub-study to Spinal Cord Stimulation to Restore Cough

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Study Protocol

Patients with cervical and thoracic spinal cord injuries often have paralysis of a major portion of their expiratory muscles and therefore, lack a normal cough mechanism (1). Consequently, most of these patients suffer from a markedly reduced ability to clear airway secretions, a factor which contributes to the development of recurrent respiratory tract infections (2,3). Since the spinal cord below the level of injury is intact in most patients, the motoneurons of the spinal cord and peripheral neuromuscular system innervating the expiratory muscles are intact. These muscles, therefore, can be electrically activated by electrical stimulation of the spinal roots to produce a functionally effective cough.

We have demonstrated that lower thoracic spinal cord stimulation (SCS), using disc electrodes, (4,5) has resulted in the generation of large positive airway pressures and peak expiratory flow rates, characteristics of a normal cough. Animal studies (performed in our laboratory) indicate that a similar response can be achieved using wire electrodes. Wire electrodes can be placed by less invasive surgical procedures, thereby reducing the surgical risks and post-operative care associated with implant of the disc electrodes. This methodology, therefore, has the potential to reach a larger population of spinal cord injured patients.

We plan to test the efficacy of temporary wire electrodes (6-8) in at least one and no more than eight study subjects enrolled in our current study ["Spinal Cord Stimulation to Restore Cough" (IRB98-00091)]. This will be done by temporarily placing the wire electrodes over the lower thoracic spinal cord. Stimulation will then be applied, and the degree of muscle contraction assessed by visual inspection and palpation over the abdominal wall and by recordings of expiratory airflow, expired volume and airway pressure. Since monopolar SCS with the disc leads, when applied in clinical trials, resulted in airway pressure generation that approximated pressures generated with a normal maximum cough, airway pressure generation achieved during SCS with these leads served as our gold standard to which all comparisons were made. If the response using the wire electrodes is similar to that of the disc electrodes, we can conclude that wire electrodes will offer an effective means of stimulation of the expiratory muscles to produce an effective cough.

Primary Aims:

To test the efficacy of wire electrodes to potentially replace disc electrodes currently being used under the IRB-approved study "Spinal Cord Stimulation to Restore Cough" (IRB98-00091).

Secondary Aims:

To determine if it is worthwhile to adapt the equipment currently in use under the IRB-approved study "Spinal Cord Stimulation to Restore Cough" (IRB98-00091) to mate with wire electrodes.

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