

Consent Form

PRINCIPAL INVESTIGATOR: Loren Fishman, M.D

DURATION OF SUBJECT'S PARTICIPATION: Twelve Weeks

I _____ agree to participate in the research study of the effect of MYOBLOC injection, which is experimental in this application, in the treatment of Thoracic Outlet Syndrome. Thoracic Outlet Syndrome involves shoulder, arm and/or hand pain, tingling, weakness or numbness as the result of pressure applied to the nerves in the neck and shoulder by the muscles and structures of the thoracic outlet in the neck and shoulder. This muscle can become so tight that the nerves are forced against the sharp edges of other structures deep in the shoulder and neck, painfully compressing the nerves, and possibly injuring them. MYOBLOC is a well-known agent used to reduce the strength of contraction of many muscles. Its use in Thoracic Outlet Syndrome is to relax the contraction of the muscles that stretch and compress the nerves at the thoracic outlet, reducing the painful compression there.

Triamcinolone Acetonide with lidocaine (steroid and anaesthetic) is also noted to reduce the strength of muscle contraction, and has been used successfully for this purpose in many muscles, including the muscles of the neck and shoulder. However, these medications are very short-lived in their effect, and the possibility of patients using them developing significant numbness and weakness is quite large.

I understand that the project will include the following procedures.

1. Initial randomized injection of 2,500 to 5,000 units of Myobloc into the thoracic outlet muscle.
2. Physical therapy twice to three times weekly for the next 12 weeks.
3. Repeat history and physical examinations at 2, 4, 6, 8, and 12 weeks after the initial visit.

I understand that the initial injections are prerandomized and blinded. That is, neither the physician nor I will know whether I am receiving 2,500 units or 5,000 units of Myobloc in the injection. However, the support team involved in the study will know which type of injection I have received.

I understand that the possible discomforts from participation in this study are:

1. Mild, reversible pain as in commonly experienced after intramuscular injections.
2. Temporary weakness of the injected muscles.
3. Possible immunity to Myobloc, reducing the effectiveness of any future Myobloc injection.

There are no recorded episodes of serious negative reaction to Myobloc in spite of its broad use for torticollis, another neck problem, for a number of years.

I understand that the benefits of participation are:

1. A possible curing or significant long-term reduction of the painful symptoms and disability due to Thoracic Outlet Syndrome. An indirect benefit may be ability to be more comfortable, e.g., in travel or at the theater or library, for a significantly longer period of time, better athletic performance, reduced discomfort in intimate relations, and greater endurance in reading, working, and other activities.

I understand that participation in this study is voluntary.

If during the course of this study evidence of an alternate effective treatment for my disease becomes available I will be given the opportunity to choose to withdraw from the

study.

I understand that the medication Myobloc will be provided to me free of charge as a grant from the Elan Corporation of San Diego, California. I understand that use of Myobloc apart from its use in this study may result in dismissal from this study.

In case of physical injury resulting from my participation in this study, only emergency care as determined by my doctor will be made available to me without charge. I also understand that I am free to withdraw from the study at any time.

My identity and participation will be kept confidential to the extent permitted by law, although I understand that if investigational and/or medical devices subject to U.S. Food and Drug Administration Regulations are involved, it may be necessary for this consent form and other medical records to be reviewed by representatives of the FDA. The Institutional Review Board (IRB) may review patient records at any time.

I further understand that should I have any questions about this study I may call Dr. Loren M. Fishman at 212-472-5688.

For information regarding subjects' rights, and for information regarding research-related injury I understand that I may call Dr. Loren Fishman (212) 472-5688, loren@arcon-inc.com.

A copy of this consent form and lay summary has been offered to me. I have had an opportunity to ask any questions I had, and all of them have been answered to my satisfaction.

My signature below verifies that I understand and agree to participate in this study.

Subject's Name (print) _____

Signature _____ Date: _____

Witness (print) _____

Signature _____

Relationship of Witness to Subject _____

Dr. Loren M. Fishman, Principal Investigator _____

Translator: _____

Financial Disclosure:

This study is supported by a grant from Elan Pharmaceuticals Incorporated, San Diego, California. Neither Dr. Fishman nor any other investigator involved in this study has financial interest in Elan Pharmaceuticals Incorporated.

For more information, or to join the study, please call (212) 472-0077.