

Fondation **Adelis**

Technion and Tal-Center Collaboration
Impact of Integrative Medicine
on
Chemotherapy-Induced Peripheral Neuropathy
A Multi-Centered Randomized Controlled Trial

Interim Progress Report

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Introduction

The project has advanced significantly since its inception and we have successfully overcome the many challenges faced in the design and implementation of a large multi-centered clinical research such as the present one. The progress has included the following, to date:

Internal Review Board (Helsinki Committee)

Approval for the study protocol, has now been received from the three participating medical centers: the Chaim Sheba Medical Center, Tel Hashomer; Clalit Healthcare Services – Carmel Medical Center, Lin Medical Center, Haifa; and the Bnai Zion Medical Center, Haifa.

The obtaining of the Internal Review Board (IRB) approval took several rounds in order to respond to the IRB reviewer demands.

IRB approval will require renewal at the end of a year from the date of authorization (November 2018 for Bnai Zion; December 2018 for Sheba and Clalit).

The study has also been entered into the NIH site, ClinicalTrials.gov

<https://clinicaltrials.gov/ct2/show/NCT03290976>

Recruitment of the Study Nurse

Ilanit Shalom-Sharabi has now been appointed as the Study Nurse. Ilanit is a clinical nurse (RN) working at the HaSharon Medical Center of the Clalit Healthcare Services. She has been working for a number of years as a study nurse in a number of collaborative projects between the Tal Center and the Technion-affiliated medical centers, as part of her doctoral (PhD) program at Haifa University. We received special permission from the Clalit Healthcare Services (Director of Nursing) to release Ilanit from part of her workload at the HaSharon Medical Center for the purpose of this project.

Recruitment and Coordination of Acupuncture Therapists

At Bnai Zion, Tzah Nahumi, an acupuncturist was recruited specifically for this project. The recruitment process is quite complex on the organizational level, and he is active in the Oncology Department since February 2018.

In addition to the ongoing "virtual" interaction between the complementary medicine practitioners involved in the project, a day-long workshop was held at the Bnai Zion Medical Center on January 1, 2018. The workshop consisted of a review of the study proceedings; discussion on the implementation of the "formula" acupuncture points to be used in the treatment group (vs. controls); and identifying

potential difficulties which may arise during the study, as well as ways in which they can be resolved. A WhatsApp group of the participating acupuncturists has been established and it is active with relevant articles and techniques to treat neuropathy. This is a significant accomplishment.

Early Publication

This project has been planned for a two-year period, at the end of which the findings will be analyzed and published in a peer-reviewed medical journal. However, as part of the preparation of the protocol, a preliminary study examining the effect of acupuncture and other complementary medicine modalities was undertaken as part of the ongoing registry protocol study at the Lin Medical Center in Haifa. The article, titled "Effect of a Complementary/Integrative Medicine Treatment Program on Taxane-Induced Peripheral Neuropathy: A Brief Report", was accepted for publication by the International Journal of Gynecological Cancer, pending minor changes. The article contains an acknowledgment of the support from the Adelis Foundation. We will forward a copy of the article to you upon its publication.

Starting the Study

Following a lengthy process with Tel Hashomer Hospital administration, we have bought Von Frey sensory assessment tools from the USA and await their arrival. This will allow us to conduct the physical assessment of the patients.

We are now commencing the recruitment of patients.

The Technion and the Tal Center
extend appreciation to

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for its support of this collaborative project

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Technion Financial Statement as of February 2018

	\$	\$
INCOME		
Donation received from The Adelis Foundation		98,376
EXPENDITURE		
Employment of Laboratory Worker	13,142	
Employment of Acupuncture Practitioners (Bnei Zion)	26,015	
Employment of Dr. Gressel	25,849	
Total Expenditure		65,006
Balance of Fund Available		\$33,370



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Tal Center Financial Statement as of April 2018

	\$	\$
INCOME		
Donation received from The Adelis Foundation		98,376
EXPENDITURE		
Employment of Acupuncture Practitioner (Tal Center)	3,486	
Von Frey Sensory Testing Kits (x4)	2,113	
Total Expenditure		5,599
Balance of Fund Available		\$92,777