Official Title of Study: -

EFFECT OF CRYOTHERAPY INCONTROLLING PERIPHERAL NEUROPATHY IN PEDIATRIC TUMOR PATIENTS

Document Date: - 08/27/2020.

Human Subjects protection review board approval date: - 12/01/2019

FACULTY OF PHYSICAL THERAPY
APPLICATION FOR ETHICAL REVIEW

NOTES:

- Answers to questions must be entered in the space provided.
- An electronic version of the completed form should be submitted to the Research Ethics Officer, at the following email address: …ethical@pt.cu.edu.eg……. Please **do not** submit paper copies.
- If you have any queries about the form, please address them to the Research Ethics Team.

FACULTY OF PHYSICAL THERAPY APPLICATION FOR ETHICAL REVIEW	*OFFICE USE ONLY:* Application No: Date Received:

1. TITLE OF PROPOSAL

EFFECT OF CRYOTHERAPY INCONTROLLING PERIPHERAL NEUROPATHY IN PEDIATRIC TUMOR PATIENTS

2. THIS PROPOSAL IS:

Physical TherapyStaff Research **Proposal** ☒

Physical TherapyPostgraduate Research (PGR) Student Proposal ☐

Master ☐ Doctoral ☐ Other ☒

Other ☐ (Please specify):

3. INVESTIGATORS

a) PLEASE GIVE DETAILS OFStudent(FOR PGR STUDENT PROPOSAL)or first author for staff Research Proposal

Name: Title / first name / family name	Hebaahmedmetwally
Highest qualification & position held:	Lecture of physical therapy/ faculty of physical therapy
Department/Faculty/ University	Cario University
Telephone:	01289213128
Email address:	Dr_hobi@yahoo.com

a) PLEASE GIVE DETAILS OF ANYCO-SUPERVISORS ORCO-INVESTIGATORS (FOR PGR STUDENT PROPOSAL) or co- first author for staff Research Proposal

b)

Name: Title / first name / family name	Nehadahmedyouness abo-zeid
Highest qualification & position held:	Lecture of physical therapy/ faculty of physical therapy
Department/Faculty/ University	South Vally University
Telephone:	01223265216
Email address:	Dr.nona77@yahoo.com

Name: Title / first name / family name	
Highest qualification & position held:	
Department/Faculty/ University	
Telephone:	
Email address:	

Name: Title / first name / family name	
Highest qualification & position held:	
Department/Faculty/ University	
Telephone:	
Email address:	

4. SUMMARY OF PROPOSAL

PURPOSE:

This study aimedassess the efficacy of cryotherapy in controlling Peripheral Neuropathy in pediatric tumors patients

BACKGROUND:

Peripheral neuropathy is a serious condition characterized by symmetrical, distal damage to the peripheral nerves that may be caused by several classes of drugs, including chemotherapeutic agents. Chemotherapy-induced peripheral neuropathy (CIPN) is an adverse effect estimated to occur in up to 40% of patients undergoing chemotherapy, with its incidence increasing in patients being treated with multiple agents. Pharmacists play a pivotal role in the prevention and management of CIPN by recommending evidence-based pharmacologic and non pharmacologic strategies appropriate for the individual patient.Peripheral neuropathy (PN) is a systemic disease characterized by symmetrical, distal damage to the peripheral nerves that negatively impacts patient quality of life (QOL). Prolonged symptoms associated with PN can cause pain, interfere with functional ability (e.g., dressing, driving, house-work), and disrupt emotional health.

HYPOTHESES:

H0 there is no significance difference of cryotherapy in controlling Peripheral Neuropathy in pediatric tumors patients

H1 there is a significance difference of cryotherapy in controlling Peripheral Neuropathy in pediatric tumors patients

RESEARCH QUESTION:
Is there is significance difference of cryotherapy in controlling Peripheral Neuropathy in pediatrictumors patients?

5. CONDUCT OF PROJECT

Please give a description of the research methodology that will be used

- Nerve conduction studies (NCS) and somatosensory-evoked potentials (SSEPs) were used to assess peripheral neuropathy pre and post intervention.
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6. PARTICIPANTS AS THE SUBJECTS OF THE RESEARCH

Describe the number of participants and important characteristics (such as age, gender, intellectual ability etc.). Specify any inclusion/exclusion criteria to be used.

Subjects:

Eighty children with tumors were enrolled in this study and were assessed for eligibility. Their aged ranged from six and fourteen years. They were assigned randomly into two equal groups. Group (A) study group received the same medical care and shockwave, three times / weak for three successful months. And group (B) control group received medical care and standard chemotherapy only.Nerve conduction studies (NCS) and somatosensory-evoked potentials (SSEPs) were used to assess peripheral neuropathy pre and post intervention. All children were assisted before and after three months of intervention.

Inclusion criteria:

1. Their age will ranging from six to fourteen years.
2. Childrenparticipated in this study will from both sexes.
3. Children receiving chemotherapy as primary treatment, postoperative surgical removal of tumors or with conjunction with radiotherapy
4. All children have polyneuropathy caused by chemotherapy.

Exclusion criteria:

1. Children with Epilepsy.
2. Children with blood clotting disorder.
3. Children have Open wounds / broken skin
4. Children with severe cardiac disease
5. Uncooperative patients.

7. RECRUITMENT

Please state clearly how the participants will be identified, approached and recruited.

Note: Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.

The patients will be recruited from Outpatient Clinic of faculty of medicine, South Vally University.

8. CONSENT

Describe the process that the investigator(s) will be using to obtain valid consent. If consent is not to be obtained explain why**.** If the participants are minors or for other reasons are not competent to consent, describe the proposed alternate source of consent, including any permission / information letter to be provided to the person(s) providing the consent.

I am freely and voluntarily consent to participate in a research program under the direction of M.Sc.
A thorough description of the procedure has been explained and I understand that I may withdraw my consent and discontinue participation in this research at any time without prejudice to me.
Date Participant

إقرار

أقر انا الموقع أدناه أني وافقت علي الأشتراك في برنامج البحث تحت إشراف الباحث
وقد تم شرح خطوات البحث بالتفصيل ولي الحق من أن انسحب من الدراسة في أي وقت أثناء
المشارك التاريخ

Note: Attach a copy of theConsent Form, Participant Information Sheet (if applicable).

PARTICIPANT WITHDRAWAL

a) Describe how the participants will be informed of their right to withdraw from the project.

Allparents will sign a written consent form after receiving information about the study purpose, whole procedures, possible benefits, privacy and use of data to ensure full cooperation. parents well understand that they may withdraw their consent and discontinue participation in the research at any time without prejudice to them.

b) Explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant's data if they withdraw.

All data of withdrawn participant will be excluded form analysis.

9. CONFIDENTIALITY

a) Will all participants be anonymous? **Yes** ☒ **No** ☐
b) Will all data be treated as confidential? **Yes**☒ **No** ☐

Note: Participants' identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant.

10. SIGNIFICANCE/BENEFITS

Outline the potential significance and/or benefits of the research

The use of freezing temperatures for analgesia has been recorded for thousands of years. Modern cryotherapy has slowly become a well-established treatment option for peripheral neuralgias and neuropathic pain conditions. Cryoneurolysis induces peripheral nerve damage and causes nerves to undergo axonotmesis followed by Wallerian degeneration. Nerve regrowth occurs but may not lead to permanent pain relief. The therapy continues to be optimized and is best used for well-defined small nerves that are easy to target. The use of cryotherapy has been indicated for intercostal neuralgia, occipital neuralgia, trigeminal neuralgia, phantom limb pain, obturator neuralgia, genitofemoral neuralgia, and intractable perineal pain.

11. RISKS

Outline any potential risks to **INDIVIDUALS**, including research staff, research participants, other individuals not involved in the research and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap

All patients will be given an explanatory session before starting evaluation procedures to be aware about different steps of test.

12. DECLARATION BY APPLICANTS

I submit this application on the basis that the information it contains is confidential and will be used by the Faculty of Physical Therapy for the purposes of ethical review and monitoring of the research project describedherein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

I declare that:

- The information in this form together with any accompanying information is complete and correct to the best of my knowledge and belief and I take full responsibility for it.
- I will report any changes affecting the ethical aspects of the project to the Faculty of Physical Therapy Research Ethics Officer.
- I will report any adverse or unforeseen events which occur to the relevant Ethics Committee via the Faculty of Physical TherapyResearch Ethics Officer.

Name of Principal investigator/project supervisor:	Dr Hebaahmed metwally
Date:19/11/2019	