01/MAY/2014

INFORMED CONSENT

Assessment of intercostal block scheduling in preventing acute surgical and post-surgical pain in thoracoscopic surgery

Entrepreneur : Dr. Dan Levy Faber

Address : Medical cente Carmel St. Michel 7, Haifa , 34362

Site of the study : Department Surgery chest House Patients Carmel

Principle Investigator: Dr. Dan Levy Faber

I am the signatory [1] Staff：

First name：

Last Name：

ID number：

Address：

Postal Code：

(1 Hereby declare that I agree to participate in a clinical trial, as specified in this document .

(2 Hereby declare that I do not participate at the time of signing this document in another clinical trial involving the use of any research product , And that I am You undertake not to participate in any other medical experiment involving the use of a research product for any duration This trial period .

(3 Hereby declare that it has been explained to me by：

Name of researcher explaining：

(3.1 that the Principal Investigator (s): Dr. Dan Levy Faber Received from the medical institution, the rights to The experiment, as defined in the Public Health Regulations (Medical Experiments on Human Subjects 1980 - 1980) , below is the clinical trial .

(3.2 that the Principal Investigator and the Sub-investigators There is affinity [2] I Zem experiment [3] . If there is ,

The lead investigator is the initiator of the study

(3.3 that the clinical trial was conducted in respect of : Evaluation of interstitial block timing in the prevention of surgical pain and acute surgical resection in torsoectomy

(3.4 that I am free to choose not to participate in the clinical trial, and that I am free Lhfsi K. anytime my participation

In the experiment, all without prejudice to my right to receive the usual treatment .

(3.5 that in the case of filling out a questionnaire - I may not answer all the questions in the questionnaire or some of them .

(3.6 that I am assured that my personal identity will be kept confidential by all those involved and involved in the research and will not be published

In all publications, including in scientific publications .

(3.7 that regulate the medical institution operated adequate insurance coverage of researchers, doctors and medical staff

Who engage in the clinical trial against claims filed by clinical trial participants and / or third party claims ,

Which are associated with the clinical trial between the period of the experiment and thereafter. This does not violate my rights to

According to any law .

(3.8 that the Zem experiment will provide the product free of charge for the duration of the study and bear in trial costs

The additional trial arising therefrom, provided that these costs do not arise standard medical treatment

The disease .

(3.9 that if necessary, according to the recommendation of the Principal Investigator, I may continue to receive the research product free of charge even after the completion of the clinical trial for a period of three years, when I have not received suitable alternative medical treatment. This is, inter alia, provided that the product has not yet been approved for the use of the indication requested in the trial in the State of Israel, and can not be obtained from the health services in which I am insured. The decision regarding the continued provision of the research product rests with the institutional Helsinki Committee, all subject to the existence of a treatment and follow-up plan .

(3.10 that I am willing to answer questions raised by me and the possibility of consulting with another party (eg

Doctor-family, family, etc.), which for the decision to participate in the clinical trial and / or to proceed .

(3.11 that in clinical trials involving women of childbearing age, in the case of pregnancy during the clinical trial, the woman will be consulted (by the researcher) regarding possible effects on the fetus and the fate of the pregnancy, including the possibility of termination of pregnancy .

(3.12 that in any problem related to the clinical trial , Dr. Dan Levy Faber

In Phone / Mobile : 04-8250289 050-3774877 , at all hours of the day .

I must immediately inform the doctor of the above details of any medical problem, injury, or other health event that may occur Related to research. If I suffer as a result of my participation in the study, I should contact the research physician for appropriate medical care and further details of my rights in this regard. Signature of this form does not derogate from my rights under the law .

(4 Declares that I have been provided with detailed information about the clinical trial , according to the following issues :

(4.1 General background and importance of the experiment . Chest surgery has been considered for many years in patients with high levels of pain. The most common approach today to treat surgical pain in postoperative breast surgeons is by inserting local anesthetic materials through epidural catheters or catheters between the ribs. In recent years there has been a significant change worldwide for this breast surgery with surgery Htorkoskofim entry (minimally invasive procedure). These surgeries significantly reduce the impact on the chest wall and therefore patients have significantly lower levels of pain. The surgical pain balance after a Turkoscopic surgery is an unresolved issue. While it is assumed that the nozzle epic Dorli or permanent intercostal catheter are Hcrhim good pain control another Torkoskofih no agreement or what is now the preferred techniques for better control of pain in this patient group. In light of this, we would like to examine one of the conventional methods of conventional block block as an addition to the anti-pain regimen accepted in the department .

(4.2 The purpose of the experiment . The study will try to determine the best timing for the injection of a drug called marquin (BUPIVAC AINE) Between the ribs to reduce pain during and after surgery. The injection of this drug will be performed at the beginning or end of the surgery .

4.3 Number of participants in the experiment . The experiment will include about 60 participants

(4 .4 the period is expected to continue participation in the trial. The duration of the trial is from the surgery stage to the first check in the clinics after the discharge from the department .

(5 .4 Methods - product description and research, a brief description of the various procedures during the trial period (treatment

And follow-up), with a clear distinction between the research procedures and the usual procedures in medicine, the chances of the participant receiving each of the treatments proposed in the trial (including placebo .(

The study will attempt to assess the quality of pain balance during surgery and in postoperative postoperative period in patients after thoracoscopic surgeries that receive an injection of a drug called Markaine (BUPIVACAINE) Which is an accepted painkiller. So by comparison between the two groups accounted. The control group will undergo interstitial block surgery at the end of the surgery and will continue pain-relief treatment according to a permanent departmental protocol given after these surgeries. In contrast, the study group will pass the interstitial block at the beginning of the operation immediately after entering the chest. Further study group will be handled without changing the balance of pain protocol currently accepted. It should be emphasized that all patients will be treated by a block between the ribs, and the difference is only in timing the execution of the block .

(6 .4 the expected benefits to the participant or to others, experimental results .

No benefits

And (d) the known risks and / or inconvenience to the participant in the study . To the extent that there is a clinical trial Risk to the participant - an explanation of the medical treatment he will receive in the event of harm to his health and the responsibility to give him .

The study does not change the regular pain-relieving treatment provided by the department and therefore no special risks are expected for the participant .

(8 .4 N. reasons which could stop the clinical trial investigator's decision or Hi Zem .

A patient coming out of a study will come during the operation and a transition from a minimally invasive (minimally invasive) torso surgery will be necessary .

,(9 .4 as applicable, the investigator shall provide to the participant information on possible medical consequences of the decision to cease participating in the clinical trial before the end .

At any stage prior to the operation, the participant may cancel his / her participation in the study without injury or change in the treatment protocol prescribed by the department .

(10 .4 Explanation Alternative treatments, and their advantages and disadvantages, if any, to the participant .

with no

(1 4.1 Other relevant information (as provided by the experiment . (

with no

(5 Hereby declare that I have given my above consent of my own free will and that I have understood all of the aforesaid above. In addition , I received a copy of this informed consent form , duly signed and signed .

(6 Upon signing this Consent Form, I authorize the Clinical Trial Committee, the Institutional Ethics Committee, the Medical Institution Auditor and the Ministry of Health to directly access my medical records to validate the trial methods Medical and clinical data. This access to my medical information will be confidential, in accordance with the laws And to procedures of confidentiality .

(7 A description of this medical experiment will appear on the website: www.clinicaltrials.gov , As required by American law and by the Israeli Ministry of Health. This site will not contain information that can identify you. At most, the website will include a summary of the results. You can search this site at any time .

(8 In cases where the clinical trial involves the provision of services: medical tests or the provision of accessories, preparations or implants, I declare that I know and agree that the information about my participation in the clinical trial will be transferred to my healthcare professional in which I am insured . I am aware that the health services will not use this information for any other purpose, except for the purpose of medical treatment and follow-up only .

Name of the participant in the clinical trial

Signature of the participant in the experiment

date

If necessary [4 [

Name of the independent witness

ID number

Signature of witness

date

Statement of the Investigator / Sub-Investigator：

The above agreement was made by, after I explained the clinical trial participant all of the above and have verified that all the explanations were understood by him．

Name of researcher explaining

Signature, seal and No. License

date

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10/02/2015

Form 2A Hebrew

version Version

Version Date Version D ate

[1] The form is written in the masculine form for convenience only and is intended for both sexes .

[2] A relationship of the wage transaction, commercial or business relationship, family or personal connection, and any other connection , including a link of subordination at work, which raises the suspicion of a conflict of interest or dependence .

[3] If the lead investigator is also the initiator of the experiment, it should be noted explicitly and the essence of the relationship should be specified .

[4] In the event that the trial participant or his legal representative is unable to read the informed consent form, an independent witness must be present during the explanation of the nature of the clinical trial. After the participant or his legal representative has expressed his oral consent to participate in the experiment, the witness will sign the consent form, indicating the date of signature.