18.03.2021

EVALUATION OF PRESSURE INJURY PREVENTION CARE BUNDLE APPLICATION IN INTENSIVE CARE UNIT PATIENTS DIAGNOSED WITH INTERNAL DISEASES

INFORMED CONSENT FORM

NCT ID: Not yet assigned

UNIVERSITY OF HEALTH SCIENCES
HAMIDIYE CLINICAL RESEARCH ETHICS COMMITTEE

INFORMED CONSENT FORM

Name of the Research Project: Evaluation of the Application of Pressure Injury Prevention Care Bundle in Internal Intensive Care Unit Patients

Name of Responsible Researcher: Assoc. Prof. Dr. Selda ÇELİK

Name of Other Researchers: Gülnaz ALTAŞ

Supportive (if applicable):

You have been invited to take part in a study called "Evaluation of Pressure Injury Prevention Care Package Implementation in Internal Intensive Care Patients". The reason why you were invited to this study is that you are being followed in intensive care. This study is conducted for research purposes and participation is voluntary. We would like to inform you about the research before you decide to participate in the study. Once you are fully informed about the study and your questions have been answered, you will be asked to sign this form if you wish to participate. This research is under the responsibility of Assoc. Prof. Dr. Selda ÇELİK at the Department of Internal Medicine Nursing, University of Health Sciences.

What is the purpose of the study; How many people besides me will participate in this study?

- The aim of the study is to reduce or prevent the development of pressure injury by using a pressure injury prevention care package in intensive care units.
- The study is single-centered and will be conducted on 98 volunteers, including 49 intervention groups and 49 control groups.

Should I participate in this study?

Whether or not you take part in this study is entirely up to you. Even if you sign this form right now, you are free to stop working at any time without giving a reason. If you do not wish to participate or leave the study, your doctor will implement the most appropriate treatment plan for you. In the same way, the doctor who conducted the study may decide that it will not be beneficial for you to continue the study and may exclude you from the study, in which case the most appropriate treatment will be selected for you.

What awaits me if I participate in this study?

The following information should be included under this heading:

- During the research period, the data will be obtained by observation.
- Duration of the research: It will take 5 months.

Are there risks and inconveniences of the study?

1. We will take any necessary medical action in case of possible harm due to the research; all expenses in this regard will also be borne by us

What are the benefits of my involvement in the study?

1. With this study conducted to determine the effect of the care package application in preventing pressure injury, the use of the package in other patients will become widespread and pressure injury will be prevented.

How much does it cost for me to participate in this study?

By participating in the study, you will not be burdened with money and you will not be paid.

How will my personal information be used? (This section will be retained)

Your study doctor will use your personal information to conduct research and statistical analysis, but your credentials will be kept confidential. Only if necessary, ethics committees or official authorities can examine the information about you. At the end of the study, you have the right to request information about your own results. The results of the study may be published in the medical literature at the end of the study, but your identity will not be disclosed.

Who can I contact for more information?

If you need additional information about the study, please contact the person below.

NAME: Gülnaz ALTAŞ

POSITION: Nurse

PHONE: 05437885406

(Participant's/Patient's Statement)

In the Department of Internal Medicine Nursing, Assoc. Prof. Dr. Selda ÇELİK and Nurse Gülnaz ALTAŞ stated that a medical research would be carried out and the above information about this research was conveyed to me and I read the relevant text. After this information, I was invited as a "participant" in such a study.

I have not encountered any compelling behavior in my participation in the research. I also know that if I refuse to participate, it will not bring any harm to my medical care and my relationship with the physician. I can withdraw from the research without giving any reason during the execution of the project. (*However, I am aware that it would be appropriate for me to inform in advance that I will withdraw from the research in order not to leave the researchers in a difficult situation).* I may also be excluded from research by the investigator provided that no harm is done to my medical condition.

I do not take any monetary responsibility for the expenses to be incurred for the research. I will not be paid either.

I know that personal information about me obtained from the research will be kept confidential.

I was given the necessary assurance that if any health problem arises due to reasons arising from the research practice, all kinds of medical interventions will be provided. (I will not be burdened with money with regard to these medical interventions either).

When I encounter a health problem during research; I know that I can call Nurse Gülnaz ALTAŞ (05437885406, Haydarpaşa Numune Training and Research Hospital) at any time.

I have understood in detail all the explanations made to me. Under these circumstances, I agree to participate in this clinical trial voluntarily, voluntarily, without any pressure or coercion.

I will be given a copy of this signed form paper.

Participant

Name, surname:

Address:

Tel:

Signature:

History:

Nurse who met with the participant

Name, surname, title: Gülnaz ALTAŞ

Address: Selimiye Mahallesi Kavak İskele Caddesi. No: 28 Daire: 5 Uskudar/Istanbul/TURKEY

Phone: 05437885406

Signature:

History: