INFORMED CONSENT FORM

PLEASE READ CAREFULLY!!!

You have been invited to participate in this study. Before agreeing to take part in this study, you must understand the purpose of the study and make your decision freely after this information. Please read this information specially prepared for you carefully and ask for clear answers to your questions.

What is the name of this study?

Comparative evaluation of external chest wall fixator effectiveness in patients with rib fractures

What is the purpose of this study?

The aim of the study is to shorten the healing time in cases of rib fractures by external fixation with the help of orthosis, increase comfort, reduce the level of pain, provide a significant decrease in the time it takes for patients to return to daily life, and reduce the negative situations that may develop in patients due to rib fractures.

What kind of application will be given to you?

If you are in the volunteer group, you will be given standard drug treatment (painkillers, antibiotics, expectorants) as in other patients with rib fractures. In addition, the "Chrisofix External Fixator" fixation orthosis will be attached to the rib rib-fracture area from the outside. If you are in the control group, standard treatment for rib fractures (painkillers, antibiotics, expectorants) will be applied.

What is the probability of random assignment to research groups for different treatments?

In this study, one patient will be assigned to the volunteer group (the group to which the fixation orthosis will be applied), while the next patient will be assigned to the control group (the group to which standard drug treatment will be applied), respectively, according to the time of admission to the hospital.

How much time will it take?

The study includes hospitalization and outpatient clinic controls. “Chrisofix External Fixator” will be applied for 10 days. Your pain levels and comfort will be evaluated when you are hospitalized, when you are discharged, at your outpatient clinic check-up 1 month later, and when you start working.

What is the estimated number of volunteers expected to participate in the study?

34

What will happen to the biological materials taken from you and where will the analyzes be done? (explaining where the biological materials will be sent if the analyzes are carried out abroad)

No biological material will be taken from you for research.

What is expected from you? What are your responsibilities?

What is expected from you, if you are in the volunteer group, is to use the "Chrisofix External Fixator" in the manner and for the time described for you and to come for regular check-ups for both groups.

How will participating in the study benefit you?

If the treatment method investigated in this study you participated in is effective, the patients' pain due to rib fractures will decrease, their comfort will increase, the duration of hospital stay will be shortened, and the time for returning to daily life will decrease. In addition, risks such as infection caused by long hospital stays will decrease.

Could participating in the study cause you any harm?

No, participating in the study cannot cause you any harm.

What happens if you don't want to participate?

There will be no sanctions if you do not want to participate in the study. In this case, you will continue to receive standard treatment.

What are the alternative methods that can be applied to you?

The alternative treatment method other than the application of "Chrisofix External Fixator" is standard drug treatment (such as painkillers, antibiotics, expectorants).

Are there any anticipated risks or discomfort that you will be exposed to during the research?

It is not anticipated that volunteers will be exposed to any risks or discomfort during the research.

Will I be paid anything for participating in this study?

No

Will I pay any fee for participating in this study?

Any examination, physical examination and other research expenses will not be paid to you or to any public or private institution or organization you are under the guarantee of.

Confidentiality of information: All your personal and medical information will remain confidential and will be used only for scientific purposes. Your identity will remain confidential even if the research results are published.

Contact information of the person responsible for this study

1- **Name, surname:** Gizem Kececi Ozgur
2- **Phone number:** 0506 678 71 28
3- **Institution:** Ege University Faculty of Medicine, Department of Thoracic Surgery

Consent to Participate in the Study:

I read and listened orally to the information above, which shows the information that must be given to the volunteer before starting the research. I asked all the questions that came to my mind to the investigator, and I have understood in detail all the explanations given to me, both written and verbal. I was given sufficient time to decide whether I wanted to participate in the study. Under these circumstances, I authorize the research conductor to review, transfer and process my medical information and I accept the invitation to participate in the research in question voluntarily, without any coercion or pressure. I know that I participated in the research voluntarily and that I can withdraw from the research at any time, with or without a reason. I know that by signing this form, I will not lose the rights provided to me by local laws.

I understand that I will be given a signed and dated copy of the informed consent.

VOLUNTEER'S		SIGNATURE
Name & Surname		
Date		

Parent or guardian for those under guardianship		SIGNATURE
Name & Surname		
Date		

A competent researcher who is part of the research team and provides information about the research		SIGNATURE
Name & Surname		
Adress		
Phone number		
Date		