AGENCJA BADAŃ MEDYCZNYCH

Polska Sieć Badań Klinicznych

Template of information about the study and informed consent form for participation in a medical experiment for an adult participant

Information for the participant and informed consent form for participation in a medical experiment

Title of the medical experiment: Carbon Fiber Transpedicular Screws in Treatment of Spinal Metastatic Disease and Stereotactic Radiotherapy - a prospective, randomized trial

Protocol: version 1.2, date 04/06/2024

Name and surname of the principal investigator: Kamil Krystkiewicz, MD, PhD

Telephone number of the principal investigator: +48 42 689 53 41

Center details: Copernicus Memorial Hospital in Łódź, Pabianicka 62, 93-513 Łódź

Sponsor's name : Copernicus Memorial Hospital in Łódź

Name and surname of the medical experiment participant :
.....

This informed consent form consists of two parts:

- **Information for the participant (containing information about the medical experiment),**
- **Declaration of consent to participate in the study (to be signed if you agree to participate in the study) with attachments in the form of consent to the processing of personal data of the medical experiment participant.**

You will receive a full copy of the informed consent form.

PART I: Information for participants in a medical experiment

Introduction

You have been invited to participate in a study titled: "Carbon Fiber Transpedicular Screws in Treatment of Spinal Metastatic Disease and Stereotactic Radiotherapy - a prospective, randomized study" because you were diagnosed with a spine tumor suspected of being a metastasis of cancer. You do not have to decide today whether you want to take part in the study. Before making a decision, you can talk to anyone of your choice about the study.

If the document contains terms you do not understand, I will explain any terms you do not understand. If you have any questions later, please ask me, the examining physician, or a member of the research team.

The study will be carried out at the Copernicus Memorial Hospital in Łódź, in accordance with the requirements of "Good Clinical Practice" (ICH GCP) and the ethical principles contained in the Declaration of Helsinki and its supplements, as well as in accordance with Polish law. All medical experiments are submitted to the Bioethics Committee for scientific and ethical opinion. The design of this medical experiment was verified by the Bioethics Committee of the Polish Mother's Health Center in Łódź and received a positive opinion. The Bioethics Committee is a group of people - specialists from fields of medicine, pharmacy and law, ethical and philosophical sciences, and representatives of patient organizations whose task is to protect research participants against harm/harm that may be associated with the research.

Purpose of a medical experiment

Cancer metastases to the spine constitute a serious clinical problem oncology. Bones are the third most common organ where metastases are located, and the spine is the element of the skeleton where they are most often located. The natural history of metastatic spine disease is the remodeling of normal bone structure. These changes increase the susceptibility of the affected bone elements of the spine to fractures, even under slight loads. Surgical treatment is undertaken in cases of spinal cord compression, instability, spinal deformity or pain resistant to radiotherapy. The standard treatment in most cases is spinal instrumentation using screws screwed into the spinal bodies, connected by a rod locked with nuts. The basic material from which the implants are made is titanium alloy. Unfortunately, this material is a material that distorts the image obtained from computed tomography or magnetic resonance imaging. They make further planning of radiotherapy and determining the optimal dose that would avoid healthy tissues as well as postoperative check-ups aimed at assessing local recurrence difficult. As a solution to this problem, we see the use of X-ray transparent implants based on carbon fibers, which do not cause image distortion typical of titanium implants. According to current knowledge, both stabilization methods are biomechanically equivalent, however, the use of carbon systems brings additional benefits to the patient in the form of easier and more effective planning of further treatment (radiotherapy) and more effective diagnosis of disease recurrence or progression.

Obligations related to participation in a medical experiment

The participant will be obliged to: attend appointments and undergo all procedures related to the study, inform the study staff about your well-being and observed symptoms, not participate in any other study, inform the staff if there is a suspicion that you are pregnant/if you your partner is pregnant, follow the recommendations, complete the questionnaires in accordance with the instructions received, etc.

It is important that when deciding to participate in the study, you accept its course and purpose and are ready to participate in it until it ends or you withdraw your consent to participate. Until you complete and sign the informed consent form below, none of the study procedures will be performed on you.

Selection and number of participants and conditions of participation in medical experiment

We invite adult patients diagnosed with a spine tumor to participate in the study. The study will involve 226 participants. It was assumed that this is the minimum number of participants necessary to perform statistical calculations in accordance with medical experiment protocol. If, during the implementation of a medical experiment, it turns out that a potential research participant will experience events/factors that prevent further participation in the study (so-called exclusion criteria) or the risk for the participant related to participation in the study increases, the principal investigator may exclude the participant from the study, despite prior qualification.

Voluntary participation in a medical experiment

Your participation in this study is completely voluntary. The decision to participate is yours. Regardless of the decision made, the hospital will continue to provide you with services - nothing will change in this respect. If you choose to participate in this medical experiment, we will provide you with the treatment that this hospital routinely offers to patients with metastatic disease to the spine - details of which are provided later in this document. You may change your mind and choose not to participate, even if you have agreed to participate now him.

Types of research interventions

Various management strategies are used in metastatic disease to the spine. One of them is surgical intervention involving the removal of tumor infiltration causing compression of neural structures and the restoration of spine stability using implant systems implanted in the bone. Another element of treatment are various radiotherapy techniques. The study will evaluate the effectiveness of various composite materials used in stabilization systems in planning and effectiveness of radiotherapy for metastatic spine tumors. Additionally, during the study, the patient's blood and tumor tissue material will be collected to assess the expression of genes involved in the process of bone formation and bone loss.

Medical experiment procedures and protocol

Process description

Your treatment process will be in accordance with the current treatment recommendations developed by the Polish Society of Spine Surgery.

After your admission to the Department of Neurosurgery and Neurooncology, Copernicus Memorial Hospital in Łódź, further proceedings and care will be carried out according to the following plan:

a. You will be interviewed by a nurse and you will be introduced to the structure and topography of the Department.
b. Blood will be collected from you for routine laboratory tests (morphology, blood clot, ionogram, urea, creatinine, erythrocyte sedimentation rate, inflammatory parameters, total protein, albumin, Hbs antigen, antibodies against hepatitis C, blood group, hormonal tests depending on diseases). basic). The amount of blood collected depends on the number of tests and is usually several milliliters.
c. After determining your blood type, your blood will be collected again in order to protect and cross-link blood products for the procedure.
d. Depending on your needs, you will undergo an imaging test - CT of the spine, MRI of the spine, functional X-ray or scalometry (postural X-ray of the entire spine). The purpose and interpretation of each test, if ordered, will be discussed with you by your neurosurgeon.
e. The doctor will discuss with you the procedure, method of treatment, possible complications, their treatment and prevention.
f. If necessary, you will undergo tumor embolization, which will be performed by interventional radiologists on the order of a neurosurgeon. This procedure is used when the tumor is highly vascularized to reduce the risk of intraoperative bleeding. This procedure is performed in the vascular laboratory under analgosedation, i.e. partial sleep.
g. Surgical treatment is planned in the following days - surgery under general anesthesia. During surgical treatment, a 5 mL blood sample will be collected from you, enabling molecular assessment of bone turnover markers, and fragments of tumor tissue, which are routinely taken for histopathological examination. After the procedure, you will be observed by the anesthesiology team in the recovery room. After observation and no disturbing symptoms, you will be transported back to the Department of Neurosurgery and Neurooncology, where you will be further monitored by the Department staff.
h. During the first postoperative day, you will undergo a CT scan to assess the position of the implants. If the implants are positioned correctly, in-unit rehabilitation will be planned for you, aimed at improving and activating your functioning the day after the procedure. If it is necessary to reposition the implant, you will be informed about another surgical procedure under general anesthesia aimed at introducing the implants to a new place.
i. In the following postoperative days, your blood count will be routinely assessed to determine the need for transfusion of blood products. The schedule of other postoperative tests depends on the clinical course of your case.

j. Your dressing will be changed and your wound and pain assessed every day.
k. On the day of discharge, the attending physician will talk to you about the recommendations and further postoperative treatment.

Unknown procedures

Due to the fact that it is not clear whether carbon implants provide benefits over classic titanium implants in the group of patients with spinal oncology, they should be compared. Recognized scientific methods that allow for a reliable comparison of treatment results in both groups of patients is the division of subjects into different groups. This is done randomly and the process is called randomization. As a result, the patient is assigned to the appropriate group in the study, without the researcher or participant being able to influence this decision. At this stage, it should be said that each group receives the best possible therapy recognized in the process of treating spinal oncological disease, and the patient may resign from participating in the study at any stage. The purpose of randomization is to exclude a phenomenon that would non-randomly, preferentially assign patients to groups in the study. This phenomenon is unfavorable and may falsify the results of a scientific study.

The rest of the procedures used in the study are standard for the treatment process.

After completing the hospital treatment process, your further treatment will be carried out on an outpatient basis as part of visits to the Neurosurgical Outpatient Clinic of Copernicus Memorial Hospital in Łódź. The examination plan assumes visits every 3 months, during which your condition will be assessed clinically and radiologically by a specialist in neurosurgery.

In case of health problems, after discharge from the hospital, you will be able to receive medical assistance in the Emergency Room of the Copernicus Memorial Hospital in Łódź or telephone advice at +48 42 695 53 44 (medical room number of the Department of Neurosurgery and Neurooncology). If there is a need to contact researchers, the staff will discuss your clinical problem by phone and arrange a follow-up visit in the outpatient clinic or department if a physical examination is needed. If you need to be hospitalized again, you will be treated in the Department of Neurosurgery and Neurooncology according to the best state of knowledge.

If you experience side effects of drugs that are routinely used in treatment, medical and nursing actions will be taken in accordance with the current state of medical knowledge.

If you require further surgical treatment in the future, you have the right and will be treated according to the results of the examination.

During the study, with your consent, biological material (blood, tumor sections) will be biobanked. The biological material will be used only for scientific purposes and will not be used for commercial purposes. As a research participant, you have the right to view the results of a scientific study while maintaining the anonymity of the participants and maintaining their privacy.

Duration of the medical experiment

This study will be conducted for a total of 5 years. After completing hospital treatment in within a month, there will be a follow-up visit to the Neurosurgical Outpatient Clinic of Copernicus Memorial Hospital in Łódź. During this visit, your health condition, the condition of the postoperative wound and pain assessment will be assessed. In addition, the neurological condition will be assessed as part of a neurological examination. A follow-up MRI of the spine with contrast will be scheduled. Then, visits and tests will take place regularly every three months months.

At each visit, the researcher will inform you about the current test results and further planned treatment. If you receive information that may influence your decision to continue participating in the study, you will have the option of agreeing to continue participating in the clinical trial or withdrawing from the study.

Risk

Oncological procedures in the spine are high-risk procedures. Performing them is associated with the possibility of complications related to the surgical procedure - neurological deficits (weakening of muscle strength, impaired sense of touch, temperature, gait disturbances), problems with wound healing or complications of hospital care - pneumonia, thrombosis, pulmonary embolism.

All procedures used (surgical treatment, radiotherapy) are standard, typical for the treatment process of oncological spine disease.

Participating in the study does not involve any additional risk for you. The only difference between the assessed groups is the type of implant used, or rather the material from which it is made. Both products are commercially available and registered in the treatment of spine pathologies. Each of them shows good biocompatibility and no complications related to the material used have been demonstrated, apart from hypersensitivity, i.e. an allergic reaction to a given material.

If you have any doubts, you should inform the doctor and ask questions at every stage of the examination.

A team of trained doctors and nurses will supervise the entire course of the examination and your health and safety. In the event of a sudden, serious deterioration of your health or well-being related to your participation in the study, appropriate treatment will be implemented. The center is equipped with the necessary equipment needed to provide assistance in emergency cases, if necessary.

It is important that any previously unnoticeable, disturbing symptoms should be immediately reported to a doctor or nurse if they occur.

Attention:
Concealing or providing false information about your health during the qualification procedures may cause serious health complications during the examination.

All adverse events (any unforeseen medical event) will be registered, and medical staff will take the necessary actions to reduce their negative consequences.

Research Insurance and Clinical Research Compensation Fund

In case of emergency, you will receive immediate medical assistance.

If you suffer any injury as a direct result of your participation in the study, please contact the study physician or a member of his staff immediately at the number provided on the first page of this form. If you are injured during this examination, the examining physician will discuss available treatment options with you.

Appropriate insurance was purchased for the medical experiment. A copy of the insurance conditions is available on request from the examining physician.

In accordance with applicable Polish regulations, the civil liability of the research sponsor and the person conducting the research is covered by the insurance policy number COR456096 issued by the insurance company Wiener TU SA Vienna Insurance Group at ul. Wołoska 22A, 02-675 Warsaw.

Clinical Research Compensation Fund

In addition, there is a special state Clinical Trials Compensation Fund, which was established to pay compensation benefits in the event of bodily injury or health impairment as a result of participation in a clinical trial. IN In the event of the death of a clinical trial participant as a result of participation in it, the compensation benefit is payable to the non-separated spouse, first-degree relative, a person in a relationship of adoption and a person in cohabitation with the participant. This benefit is not due, in in the event that bodily injury or health impairment or death of a clinical trial participant results from the natural course of the disease. The amount of the benefit is: in the event of bodily injury or health impairment from PLN 2,000 to PLN 200,000, and in in the event of death from PLN 20,000 to PLN 100,000.

When determining the amount of the compensation benefit, the following shall be taken into account in the case of: 1) bodily injury or health disorder of a clinical trial participant - the nature of the health consequences and the degree of symptoms resulting from the bodily injury or health disorder, including the burdensomeness of treatment, health damage and deterioration of the quality of life; 2) death of a clinical trial participant - remaining in married at the time of the death of the clinical trial participant, consanguinity, adoption, cohabitation and the age of the relative/close person and the deceased clinical trial participant.

An application for a compensation benefit is submitted to the Patient Ombudsman. It may be **submitted within one year from the date** on which the applicant learned about the bodily injury or health disorder or death of the clinical trial participant, however, **this period may not be longer than 3 years from the date on which the event occurred. Submitting an application is subject to a fee of PLN 300** (subject to annual indexation), which is paid to the Fund's bank account.

Detailed information about the Clinical Research Compensation Fund (including the benefit application template and the Fund's bank account number) can be found on the website of the Patient Ombudsman. gov.pl/rpp . Questions regarding the Fund can be sent to the Ombudsman by correspondence, by writing an e-mail to kancelaria@rpp.gov.pl or by calling the free Patient Information Telephone (number 800-190-590).

Benefits

The main benefit of participating in the research project for you are regular outpatient visits scheduled by the Staff. The program includes visits to the Neurosurgical Outpatient Clinic every 3 months, including a clinical and radiological assessment of your spine.

Data confidentiality

If you decide to participate in this study, your personal data will be processed confidentially and will not be made public, and the management and use of information collected during the process is regulated by the principles contained in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27/04/2016 on the protection of natural persons with regard to the processing of personal data i free movement of this data and repealing Directive 95/46/EC (General Data Protection Regulation) - GDPR - and the Polish Act of May 10, 2018 on the protection of personal data. The processing of personal data related to health is necessary to conduct the study.

We do not inform about the identity of people participating in the study.

Information collected as part of the study will be confidential. Information collected about you as part of the study will not be available to anyone other than the researchers. All information about you will be marked with a number instead of your name. Only investigators will know what number you have been assigned, and this information will be kept locked up. We will not provide information to anyone other than Copernicus Memorial Hospital employees participating in the treatment process and involved in medical experiment.

Sharing research results, including providing a summary of the results of a medical experiment in the European Union database

We will not provide confidential information and the identity of the study participants will remain anonymous even after its completion. After completing the study, the results will be scientifically and statistically analyzed and published in medical journals and presented at scientific conferences.

The right to refuse or withdraw participation in a medical experiment

You do not have to participate in the study if you do not want to. Refusal to participate will not in any way affect your current treatment at this center. You will still be able to use the services available at this center. You may stop participating in the study at any time

and you will not lose the benefits to which you are entitled as a patient. This decision will in no way affect the treatment you receive at the center.

Contact options

If you have any questions, you can ask them now or later, even after the study has started and at any time during the study. If you would like to ask something later, you can contact the people below:

Dr. Kamil Krystkiewicz, Department of Neurosurgery and Neurooncology, Copernicus Memorial Hospital in Łódź, tel. +48 42 689 53 41;
Dr. Marcin Tosik, MD, Department of Neurosurgery and Neurooncology, Copernicus Memorial Hospital in Łódź, tel. +48 42 689 53 41 .
You can also contact the indicated persons if you wish to withdraw from the study.

If any additional information about a medical experiment appears that may affect the willingness to continue participating in the study, the doctor/researcher is obliged to immediately provide it to the participant of the medical experiment.

Persons who are participants in a medical experiment have the rights resulting from the Patient's rights included in the Patient's Charter of Rights. Information on this subject can be provided by the Office of the Patient Ombudsman, established by the Minister of Health, located at: Płocka 11/13, 01-231 Warsaw. The free Patient Information Telephone number 800 190 590 is open from Monday to Friday from 8:00 a.m. to 6:00 p.m.

Visitors are received at the office on Mondays from 9:00 a.m. to 6:00 p.m. and from Tuesday to Friday from 9:00 a.m. to 3:00 p.m. This form of contact can be used by any person who comes to the office in person for advice or information on patient rights. People interested in such a visit should register via e-mail (address: rezerwacja@rpp.gov.pl) or by phone (22 532 82 43), after which the day and time of the meeting will be set.

Obtaining advice, clarifying doubts and obtaining answers to your questions related to patient rights can also be obtained by writing to the e-mail address kancelaria@rpp.gov.pl or by sending an inquiry via the appropriate form available on the website: www.gov.pl/web/rpp/rzecznik-praw-pacjenta.

PART II: Declaration of voluntary consent to participate in the study

Declaration of the person consenting to participate in the study

I have read the above information or it was read to me. I have had the opportunity to ask questions about this information and have received satisfactory answers to all my questions. I voluntarily agree/do not agree to participate in this study as a participant.

Participant's name and surname (in capital letters)

.....

Participant's signature

.....

Date of signature

.....

INFORMATION CLAUSE CONCERNING THE PROCESSING OF PERSONAL DATA
participant in a medical experiment

Pursuant to Art. 13 section 1 and 2 and art. 14 section 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data , and repealing Directive 95/46/EC (so-called general data protection regulation (" **GDPR** "),

The administrator informs That:

1. The administrator of personal data is (contact details): Tomasz Zdziennicki (“ **Administrator** ”).
2. The Administrator has appointed a Data Protection Inspector (“ **DPO** ”). Contact with IOD: iod@kopernik.lodz.pl

Please contact us in all matters relating to the processing of your personal data.

3. Information regarding data processing in your country case:

Participating in a medical experiment

Who is affected by data processing?	Participants in a medical experiment. Your personal data was obtained directly from you or was made available to us by other medical entities in connection with the provision or intention to provide medical services or participation in a medical experiment.
Method of obtaining personal data	From Mr./Ms., the study participant.
Legal basis for the processing of personal data	• art. 6 section 1 letter c GDPR – fulfillment of legal obligation, including: regulations on archiving and keeping medical records, the Act on clinical trials of medicinal products used in people on March 9, 2023 • art. 6 section 1 letter f GDPR - implementation of the legitimate interest of the administrator; • art. 6 section 1 letter e GDPR - premises on which entities carrying out tasks in the public interest or as part of the exercise of public authority (e.g. a public entity) may rely; • art. 9 section 2 letter and GDPR - implementation of tasks related to the public interest in the field of public health; • art. 9 section 2 letter j GDPR – processing of personal data necessary for scientific research purposes; • art. 9 section 2 letter h GDPR - provision of health care and processing for health prevention purposes (research center).

Processed personal data	Regular and special category personal data in terms of identification and contact data and research documentation included in the survey, informed consent form, clinical observation card (CRF) and medical documentation. In particular, these may be, depending on the data provided by you: names and surname, residential address, PESEL (if missing - series and number or type of identity document), other contact details (telephone, email), patient identification number (in certain cases).
Purpose of personal data processing	Implementation of a medical experiment by Administrators who participate in the implementation of a medical experiment - sponsor, researcher, research center. Personal data of participants in medical experiments will be processed solely for the purpose of conducting research and to the extent necessary to achieve this purpose, as well as conducting medical activities and medical documentation required by law.
Personal data processing period	Your personal data will be stored for the period required by law for storing medical records, in accordance with the provisions of law, incl in particular art. 29 of the Act of November 6, 2008 on patient rights and the Patient Ombudsman.

4. Providing data is necessary to carry out a medical experiment. Failure to provide data will result in your inability to participate examination.
5. Entities carrying out medical experiments will have access to the personal data of participants in medical experiments only to the extent necessary to perform their tasks. These entities guarantee the implementation of appropriate technical and organizational measures to ensure the security of personal data.
6. The administrator may, in accordance with the law, transfer your data to other recipients. In the case of your medical records, the law specifies in detail who may have access to your medical records - Art. 26 of the Act on Patient Rights and the Patient Ombudsman - i The Administrator should always comply with these regulations. Apart from the issue of medical records, recipients of your personal data may to be:

    a) duly authorized associates of the Administrator or its service provider, to the extent necessary and justified, including, e.g. IT service providers, software;

    b) entities authorized to statutory or contractual control or supervision of the Administrator, including the competent minister;

    c) other entities authorized by law to supervise and control and other entities authorized by law;

    d) entities conducting scientific research and development work in the European Economic Area;

    e) entities providing maintenance or support of IT systems used by the Administrator, entities providing hosting or cloud services;

f) companies providing specialized transport;

g) courier and postal companies.

7. Your personal data will not be transferred to third countries or international organizations.
8. No decisions will be made regarding your personal data automated way. There will also be no profiling on them basis.
9. Please contact the Administrator regarding your rights. You have the right down:

   a) access to the transferred data personal data;

   b) rectification of the provided data personal data;

   c) requests to limit data processing personal data;

   d) the right to object to processing;

   e) submit a complaint to the President of the Personal Data Protection Office regarding the processing of data by the Administrator;

   f) deletion of data (right to be forgotten), in a situation where data processing does not take place in order to fulfill the obligation arising from the law;
10. Pursuant to Article 8 of the Act on Clinical Trials of Medicinal Products for Human Use of March 9, 2023, when conducting clinical trials that are scientific research, it is allowed to limit the application of the provisions of Art. 15, art. 16, art. 18 and art. 21 GDPR, if it is likely that the rights set out in these provisions will prevent or seriously impede the achievement of the objectives of a clinical trial which is a scientific investigation and if these restrictions are necessary for the achievement of these objectives.
11. Due to the obligation of confidentiality, your personal data is deprived of any identification function for the sponsor using data pseudonymization methods. Personal data processing only takes place i only in such a way that they cannot be attributed to a specific person without the use of additional information, which is stored separately as part of the medical experiment.

I authorize the Sponsor and its representatives to access my medical records in all forms permitted by law and regardless of the moment of request. granting access.

Participant's name and surname (in capital letters)

.....

Participant's signature

.....

Date of signature

.....

If the participant cannot read / is visually impaired (cross out if not applicable)

I witnessed the careful reading of participant information regarding a medical experiment and the informed consent form to participate in the study to a potential participant. This person had the opportunity to ask questions. I confirm that this person has voluntarily given his consent.

Name and surname of the witness (in capital letters)
.....

Witness signature
.....

Date of signature
.....

- *Declaration of acceptance of insurance conditions in case of damage suffered as a result of the study "Carbon Fiber Transpedicular Screws in Treatment of Spinal Metastatic Disease and Stereotactic Radiotherapy - a prospective, randomized study"*

I have been informed about the conditions of insurance for the medical experiment in the event of damage incurred as a result of the study and about the possibility of viewing the study's insurance policy.

Participant's name and surname (in capital letters)
.....

Participant's signature
.....

Date of signature
.....

Declaration by the investigator/person obtaining consent

I carefully read the patient information about the medical experiment to the potential participant of the study and made every effort to ensure that he/she understood that the study would include (please specify):
1. Surgical treatment of a spine tumor preceded by imaging diagnostics i laboratory .
2. Stereotactic spine radiotherapy .
3. Biobanking of tissue material .
I confirm that the participant had the opportunity to ask questions about the study, and I answered the questions asked by the participant truthfully and to the best of my ability. I confirm that the participant was not forced to consent and that consent was expressed freely and voluntarily.

A copy of this informed consent form was provided to the participant.

Name and surname of the researcher /person obtaining consent (in capital letters)
.....

Signature of the researcher/person obtaining consent
.....

Date of signature
.....

Declaration of consent to the storage and processing of data regarding biological material obtained as a result of a medical experiment.

Declaration of a person consenting to collecting and securing material for genetic testing as part of the study

Title of the study: Carbon Fiber Transpedicular Screws in Treatment of Spinal Metastatic Disease and Stereotactic Radiotherapy - a prospective, randomized study

Details of the main investigator: Kamil Krystkiewicz, MD, PhD

I declare that I have been informed about the assumptions, method of implementation and goals of the above-mentioned research project. I have read and understood the Information for the study participant. I had the opportunity to ask questions and I understood the answers received. I had enough time to decide to conduct molecular/genetic tests on the material collected from me and to preserve the remaining biological material for further scientific research. I understand that the confidentiality of my personal data will be maintained and that further use of biological material will remain under the control of the Bioethics Committee. I am aware that participation in the research is voluntary and consent may be withdrawn at any time. I have received a copy of the Patient Information form and the Participant Informed Consent form.

Based on Article. 6 section 1 letter a GDPR, I consent to the processing of my ordinary personal data transferred together with biological material only by the Biobank Łódź Laboratory of the Department of Molecular Biophysics, University of Łódź, Pomorska 139, 90-235 Łódź, for the purposes of scientific research and handling of biological material donated by me and pursuant to Art. 9 section 2 letter a GDPR for transfer and storage by the Biobank Łódź Laboratory of the Department of Molecular Biophysics of the University of Łódź, Pomorska 139, 90-235 Łódź, my biological material, i.e. blood and tissue, for broadly understood scientific research purposes, including projects, current and future research in the area of biomedicine and biological sciences aimed at searching for and improving medical preventive methods , diagnostic and therapeutic, which will be consistent with the requirements of Polish law, ethical standards in the field of scientific research and will be approved by the relevant bioethics committees.

Based on Article. 6 section 1 letter a GDPR and art. 9 section 2 letter a GDPR, I consent to the processing of my genetic and health-related personal data (including those resulting from medical documentation) for scientific research purposes by the Biobank Łódź Laboratory of the Department of Molecular Biophysics, University of Łódź, Pomorska 139, 90-235 Łódź, including providing anonymized or pseudonymized data (information) to entities conducting scientific research and development work in the European Economic Area - for the same purposes of scientific research.

I declare that I consent to:

1. obtain:
   - approx. 5 mL of blood and a tissue sample of the operated tumor at the beginning of the surgery,
   - a tissue sample taken during surgery,
2. storing the above-mentioned material in the form of:

(1) DNA, (2) RNA, (3) plasma in the Biobank Łódź, which is located at the Department of Molecular Biophysics of the University of Łódź, Pomorska 139, 90-235 Łódź - in terms of the possibility of using it for further scientific research aimed at expanding knowledge,

3. transfer of the necessary part of the DNA and RNA material:

from the Biobank to the MOLecoLAB Genetics Laboratory, Medical University of Łódź, in order to perform a selective genetic test of selected markers indicating the process of tumorigenesis in the spine and to determine their potential role in formation of metastases. The material will be destroyed after the test.

If you do not consent to these analyses, you will still be able to participate in the study.

I consent: **YES** **NO**

Participant's name and surname (in capital letters)

.....

Participant's signature

.....

Date of signature

.....

INFORMATION CLAUSE CONCERNING THE PROCESSING OF PERSONAL DATA

Biobanking for scientific purposes

Pursuant to Art. 13 section 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (the so-called General Regulation on data protection) (" **GDPR** "),

The administrator informs That:

1. The administrator of personal data is (contact details): Tomasz Zdziennicki (“ **Administrator** ”).
2. The Administrator has appointed a Data Protection Inspector (“ **DPO** ”). Contact with IOD: iod@kopernik.lodz.pl

Please contact us in all matters relating to the processing of your data.

3. Information regarding data processing in your country case:

Using biological material for scientific research

Who is affected by the processing?	People who have consciously and voluntarily agreed, through an informed consent form, to the use of their biological material for scientific research.
Method of obtaining personal data	From Mr./Ms., the study participant.
Legal basis for the processing of personal data	art. 6 section 1 letter a and art. 9 section 2. letter a of the GDPR - your consent.
Processed personal data	Ordinary and special category personal data provided by you, as well as genetic and health data (data provided by you that increase the scientific value of your biological material by linking it to other factors such as age, gender, lifestyle, data demographic etc.).
Purpose of personal data processing	Carrying out scientific activities by the Administrator and other entities to which the Administrator may transfer your biological material, as part of the exercise of the right to scientific freedom, on the terms specified in the informed consent form and information accompanying it. Including making them available to entities for scientific purposes.
Personal data processing period	On the above rules for medical records or until consent is withdrawn or until a time that is no longer than the achievement of the purpose of scientific research.

4. If you consent to ongoing contact or repeated contact with We will process you, your e-mail address and telephone number for the purposes of scientific research and handling your donation of biological material, scientific research and providing information relevant to your health that may appear in connection with conducting research, if it is of clinical importance (Article 6(1)(a) of the GDPR).

5. Your personal data may also be processed for the purposes and to the extent required by the provisions of generally applicable law, e.g. provisions on archiving or keeping medical records (Article 6(1)(c) of the GDPR).

6. Your data will be stored for the duration of the biobanking program or until you withdraw your consent .

7. If the law provides for a longer data processing period in any respect, this longer period shall apply.
8. Providing data is voluntary, but necessary for the implementation of a scientific study, ongoing contact or repeated contact with you, transfer of donations of biological material for scientific research purposes and handling your donation of biological material for scientific research, and transfer of information relevant to your health that may arise in connection with your health. with conducting research, if it is clinically important.
9. The administrator may, in accordance with the law, transfer your data to other recipients. In the case of your medical records, the law specifies in detail who may have access to your medical records - Art. 26 of the Act on Patient Rights and the Patient Ombudsman - and the Administrator should always comply with these provisions. Apart from the issue of medical records, recipients of your personal data may to be:
    a) duly authorized associates of the Administrator or its service provider, to the extent necessary and justified, including, e.g. IT service providers, software;
    b) entities authorized to statutory or contractual control or supervision over the Administrator, including the competent authority minister;
    c) other entities authorized by law to supervise and control and other entities authorized by law;
    d) entities conducting scientific research and development work in the European Economic Area ;
    e) entities providing maintenance or support of IT systems used by the Administrator, entities providing hosting or cloud services;
    f) companies providing specialized transport;
    g) courier and postal companies.
10. Your personal data will not be transferred to third countries or international organizations.
11. No decisions will be made regarding your personal data automated way. There will also be no profiling of them basis.
12. Regarding your rights, please contact the Administrator by e-mail. You have the right down:
    a) access to the transferred data personal data;

b) rectification of the provided data personal data;

c) requests to limit data processing personal data;

d) submit a complaint to the President of the Personal Data Protection Office regarding the processing of data by the Administrator;

e) deletion of data (right to be forgotten);

f) data transfer personal data;

g) withdrawing your voluntarily expressed consent to processing at any time - if the processing is based on consent. Withdrawal of this consent does not affect any existing processing on this basis before its withdrawal .

I hereby declare my participation in the above-mentioned scientific project.

Participant's name and surname (in capital letters)

.....

Participant's signature

.....

Date of signature

.....

Name and surname of the investigator/person obtaining consent (in capital letters)

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Signature of the investigator/person obtaining consent

.....

Date of signature

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