CONGENITAL MIDLINE ANOMALY (MENINGOCELE / MENINGOMYELOCELE)

Informed Consent Document

Form No: AOF-026 **Rev. No / Date:** 2026 v09 / 10.07.2026

PATIENT PROTOCOL NO		DATE	
TURKISH ID / PASSPORT NO		DATE OF BIRTH	
PATIENT'S FULL NAME		SEX	
DIAGNOSIS			

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1. Dear Patient,

It is your most natural right to be informed about your medical condition and about all medical / surgical treatments and diagnostic procedures recommended to you for the treatment of your illness. After learning the benefits and possible risks of medical treatments and surgical interventions, it is again your own decision to consent or not to consent to the procedure to be performed. The purpose of this explanation is not to frighten or worry you, but to involve you more consciously in the decisions to be made about matters concerning your health. If you wish, all information and documents concerning your health can be given to you or to a relative you deem appropriate. Although this form has been designed to meet the needs of most patients under many circumstances, it should not be considered a document containing the risks of all forms of treatment. Depending on your personal health condition, your physician may give you different or additional information. After learning the benefits and possible risks of diagnosis, medical treatment and surgical interventions, it is your own decision to accept or not to accept the procedures to be performed. Except in situations of legal and medical necessity, you may refuse to be informed or may withdraw your consent at any time. This form has been prepared to inform you about the risks of the surgery and about alternative treatment methods. Please read this form completely and carefully, and sign this consent form only after you have read it and all your doubts regarding the procedure in question have been resolved by the physician.

2. General Information About the Disease and Its Treatment

Congenital Midline Developmental Anomalies Surgery (DOHGA) concerns a congenital developmental deficiency involving the spinal cord. It is also commonly known as "spina bifida". Meningocele and meningomyelocele are anomalies in the form of an open or skin-covered sac that develop as a result of the failure of the spinal cord and its surrounding membranes (dura) to close along the midline of the back. The brain exerts its control over the body by means of the spinal cord. Therefore, children born with DOHGA may have disabilities ranging from very mild to very serious. The main ones are:

Partial or complete paralysis from the waist down,
Disorders in passing urine and stool,

Orthopedic disorders of various degrees (deformities of the feet, hip dislocations, curvatures of the spine),
Accumulation of cerebrospinal fluid (CSF) in the brain (which may also occur after the surgery) = hydrocephalus,
Various developmental disorders in the brain,
Anomalies of the craniocervical junction (in serious cases, these may lead to disorders of breathing, swallowing and deglutition),
Accumulation of cerebrospinal fluid (CSF) in the spinal cord,
Other accompanying organ disorders.

DOHGA is divided into two groups according to whether or not it is covered by intact skin. If the opening in the lower back is not covered by skin, the likelihood of inflammation is high. The closure defect of the spinal cord is frequently accompanied by hindbrain anomalies and by the cerebrospinal fluid circulation disorder called hydrocephalus. For this reason, in the child's later life, shunt surgeries aimed at the cerebrospinal fluid circulation and revision surgeries related to the shunt may become necessary.

I know that the surgery to be performed will not serve to correct the existing permanent disabilities in my patient. With the surgery, the region where the abnormality is located will be repaired and the tissues will be brought, as far as possible, to their appropriate anatomical positions. Patients are operated on in the prone position under the microscope after general anesthesia has been administered. I know that my doctor will make an incision over the lesion area in order to expose the region to be repaired, and may also remove a piece from the spinal (vertebral) bone in order to reach the spinal cord. This may later be one of the various causes of certain spinal curvatures. Afterwards, the membrane of the spinal cord will also be incised, and the spinal cord will be freed and released from the adhesions around it; the nerve roots adhering to the wall of the sac are separated, using microsurgical technique and the necessary equipment, without harming the patient. In some cases, the intact spinal cord membrane and intact skin may not be sufficient to cover the incision site. In this case, my doctor may patch the spinal cord membrane and the skin with a piece of tissue that is sold artificially or taken from another part of the body. In addition, other plastic surgery methods may also be used to close the skin layer. Your doctor, after evaluating your condition in detail, has decided on the most appropriate surgical treatment method for you and has recommended this approach to you.

3. Alternatives to the Surgery, If Any

As alternatives to the surgery, I have considered the following options:

As explained to me verbally by my doctor, accepting all risks and not having this surgery,
Accepting all risks and follow-up with computed tomography, magnetic resonance imaging or other examinations,
Other possible treatment options...

I have also evaluated other treatment methods explained to me by my doctor. The advantages and disadvantages of these alternative methods have also been explained to me by my doctor.

4. Expected Benefits of the Surgery

I understand that the aim of DOHGA surgeries is to perform a repair in the region of the spinal cord where there is a developmental disorder, thereby preventing the existing disorders and disabilities from worsening and paving the way for rehabilitation. In addition, by closing the sac (dura and skin), the aim is to eliminate the contact of the cerebrospinal fluid with the external environment and the consequent risk of infection (meningitis). I am aware that no guarantee is given regarding the results of this method, and I accept this.

5. Estimated Duration of the Surgery

The duration of the procedure to be performed may vary according to the condition of the disease and of the patient, and is on average ..... - ..... hours. In addition, the procedures to be performed on patients before and after the surgery by the anesthesia doctors are not included in this duration. The procedure may take longer than the stated duration depending on the condition of the case. Your doctor will give you detailed information at the end of the procedure.

6. Risks and Complications of the Surgery

In addition to the benefits of the surgical procedure to be performed, there are also risks that may arise.

Anesthesia risk: There are risks during and after local and general anesthesia procedures (due to the position given to the patient during the surgery). In addition, in every form of anesthesia and in sedation, there are also complications and harms that may occur due to the medications. The anesthesia procedure to be applied and the related risks and complications have been explained to me, and I approve the recommended procedure in this regard.

Bleeding: Although very rare, I am aware of the existence of a risk of bleeding, which may be severe, during or after my surgery. In case of bleeding, additional treatment or blood transfusion may be needed. In such a case, I approve the necessary blood transfusion and other treatments. Some medications that I use and/or that need to be used during my treatment may increase the risk of bleeding through drug interactions and/or side effects. In some cases, it may be necessary to use blood-thinning medications earlier than expected, and this may also increase the risk of bleeding.

Blood clot formation: Blood clots may form after any type of surgery. Clots forming in the bleeding area may obstruct blood flow and lead to complications such as pain, edema, inflammation or tissue damage. If the use of blood thinners is discontinued, the risk of clotting may increase.

Postoperative Neurological Deterioration: Nervous system functions may deteriorate after the surgery due to problems such as bleeding at the surgical site, brain edema (pressure on the brain as a result of fluid accumulation) or vasospasm (narrowing of the vessels).

Brain and spinal cord injury: During the intervention performed, the neural tissues (brain, spinal cord and nerves) may be damaged, and this may lead to certain functional disorders. After the surgery, accumulation of fluid in the brain, or problems related to swallowing, deglutition and breathing (Chiari malformation) may develop.

Neurological deficit (bladder / bowel / lower extremity): During surgery directed at the sac wall and the nerve roots, the nerve structures that provide the passing and holding of urine and stool as well as the movements of the legs may be affected. Consequently, bladder and bowel dysfunction (urinary/fecal incontinence or inability to hold), loss of strength in the lower extremities, paralysis and sensory disturbances may, depending on the existing condition, remain unchanged, regress or worsen.

Risk of cerebrospinal fluid leakage: After the surgery, cerebrospinal fluid may leak from the wound site to the external environment. For the treatment of this, a spinal (spinal cord) catheter or an additional intervention aimed at repairing the same wound site again may be required.

Problems related to closure of the skin and the spinal cord membrane: Despite all surgical methods, it may be very difficult to cover the incision site with intact tissue. In such cases, openings in the skin and leakage of cerebrospinal fluid (CSF) may develop.

Hydrocephalus and need for a shunt: After the surgery or in the natural course of the disease, accumulation of cerebrospinal fluid in the brain (hydrocephalus) may develop. In this case, the placement of a system called a shunt may be required in order to provide the circulation of the cerebrospinal fluid; in the later period, revision surgeries related to the shunt may also be required.

Tethering of the spinal cord (tethered cord): During the patient's follow-up, tethering of the spinal cord may occur. In this case, in order to prevent the harm that the tethering of the spinal cord would cause, additional surgeries with similar methods may be required.

Cardiac complications: The surgery carries a low risk of leading to an irregular heart rhythm or a heart attack.

Infection: Infection may occur at the skin incision site as well as in the surgical field, and even in the bone within the surgical field. Risks related to infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (accumulation of pus).

Respiratory difficulty: During surgery, due to brainstem damage, and after surgery, due to the compression effect of a clot on the brainstem or spinal cord, lung infection (pneumonia) and, due to the effect of a clot on the pulmonary artery (pulmonary embolism), respiratory distress may occur. Additional treatment may be required.

Stroke (paralysis): Although rare, weakness in the arm and/or leg may develop during or after surgery following the lodging of air or a clot in the brain from the veins. Additional treatment may be required.

Implants placed during the surgery may lead to conditions such as breakage, displacement, failure to perform their function, allergy and infection. For this reason, their removal or replacement may be required.

Increase in pain complaint: Although rare, the complaint of pain may increase after the surgery.

Recurrence: After the surgery, some of the complaints may recur in the early or late period, and in this case additional surgical intervention may be required.

Failure of the surgery: The surgical intervention to be performed may not provide the improvement of all or some of the complaints.

Death: Although very rare, there is a risk of death during or after the surgery.

I have also understood the possibility that, during my surgery, in the face of an unexpected situation such as bleeding, injury to an adjacent tissue or organ, etc., my doctor may perform other procedures required for my health apart from the planned procedure, and I approve this.

I have understood and accept all the risks written above that may occur during and after the surgical procedure to be performed on me.

7. Consequences to Be Faced If the Surgery Is Not Performed

The patient's current complaints and clinical condition may not improve, and there may be a worsening. In cases not covered by skin, the sac may rupture; if it has already ruptured, the patient may deteriorate as a result of the contact of the cerebrospinal fluid with the external environment, leading to meningitis and the disorders it causes. Accumulation of fluid in the brain called hydrocephalus may develop. The development of this condition is not due to the surgery performed; it is related to the natural course of the disease and its development cannot be prevented. During the patient's follow-up, tethering of the spinal cord may occur. In this case, in order to prevent the harm that the tethering of the spinal cord would cause, additional surgeries with similar methods may be required. This condition is related to the natural course of the disease and cannot be prevented. During the patient's follow-up, another abnormality along the spinal cord that was not intervened upon during the first surgery may be noticed or may develop. In this case, a new intervention may be required.

8. Important Characteristics of the Medications to Be Used

If you have a previously identified drug allergy, you must inform your physician and your nurse about this. During your current treatment process, medications appropriate to the patient's medical condition (painkillers, antibiotics, medications supporting the circulation and the heart, blood products, fluid therapies, medications specific to your disease) will be given according to the reason for your admission or newly developing conditions. During the use of medications, side effects may emerge and cause damage to the heart, kidneys and other organs. New medications will be added to the treatment to correct organ damage. PROPHYLAXIS: Before and after your surgery, appropriate protective antibiotic therapy is applied with the aim of reducing the risk of surgical site infection. USE OF BLOOD-THINNING MEDICATION: If you are using anticoagulant, blood-thinning medications, different medication therapies or blood products may be given to you to counteract the effects of these

medications. SPINAL CASES: In case of severe pain after spinal operations, medications sold under a green (controlled-substance) prescription, which may cause dependence, may be used. After spinal surgeries, in cases of no change in weakness in the arms and legs, or of newly developing weakness, anti-edema medications may be used. In this case, the blood sugar balance may be disturbed. SHUNT INFECTION, EVD: As a result of a CSF infection, it will be necessary to start appropriate antibiotics recommended by infectious diseases. Among these treatments, the method in which medications are applied into the brain ventricles by means of an EVD, expressed as intraventricular treatment, may also be used. INTENSIVE CARE-DELIRIUM: In elderly patients and during prolonged intensive care stays, for psychological symptoms that may emerge in patients, mental health-regulating medications recommended by a psychiatrist may be used. These medications may damage the heart, kidneys and other organs. In addition to these, medications related to anesthesia are used. The general anesthetic medications given during the surgery may have toxic (poisonous) effects / side effects on organs such as the lungs, heart, brain, kidneys and liver. For this reason, DANGER OF DEATH may arise. I have informed my doctor about all my known allergies. I have also informed my doctor about the prescription medications I use, over-the-counter medications, herbal medicines, dietary supplements, illegal drugs, alcohol and narcotics/intoxicants. The effects of the use of these substances before and after the surgery have been explained to me by my doctor and recommendations have been made. During my stay in the hospital, I have received information about the important characteristics of the medications to be used for diagnosis and treatment (what they are used for, their benefits, their side effects, how they are to be used).

9. Lifestyle Recommendations Critical for Patient Health

Tobacco and Tobacco Products: It has been explained to me that smoking tobacco and tobacco products (cigarettes, waterpipe, cigars, pipe, etc.) before or after my surgery may cause my recovery process to be prolonged. Anesthesia risks are higher in patients who smoke; death due to anesthesia is seen more frequently. If you smoke, you should know that the success of the treatment/surgery will be lower than the general success average.

Follow your doctor's recommendations (exercise, nutrition program, etc.) and, if applicable, do not neglect your outpatient clinic check-up on the date requested of you.

I have received information about what I need to do regarding my lifestyle after my treatment/surgery (diet, bathing, medication use, mobility status and/or restriction status).

10. Patient-Specific Section

*The patient's individual specific circumstances are recorded at the end of the form under **Section 14 — Signatures**.*

11. How to Access Medical Assistance on the Same Matter When Needed

Not accepting the application of the treatment/surgery is a decision you will make of your own free will. If you change your mind, you may personally reapply to our hospital/hospitals capable of performing the treatment/surgery in question.

I have received information about how to access medical assistance on the same matter when needed (my own physician, a different physician, the clinic where I was treated, and in emergencies, 112).

12. Permissions

I authorize the Head of the Surgical Team, Responsible Specialist Doctor **Dr. Özgür Akşan**, and his team to perform my surgery.

I understand that this intervention is performed with the aim of eliminating my complaints and with the intention of preserving or improving the function of the nervous system. I confirm that my doctor has explained all the information above, that I have understood this information, and that all my questions

regarding this intervention have been answered. Therefore, I give my consent for **REPAIR SURGERY FOR CONGENITAL MIDLINE ANOMALIES (MENINGOCELE / MENINGOMYELOCELE)** and for all different or additional surgeries and additional treatment interventions deemed necessary by my doctor.

Use of tissue: Any tissue not required for medical diagnosis may be used for medical research within the framework of ethical rules. I give my consent to the use of any tissue, medical device or body parts that may have been removed during the surgical procedure.

Medical research: I give my consent to the review of clinical information from my medical records for the advancement of medical study, medical research and doctor training, provided that confidentiality rules are observed.

Photography/Observers: I consent to the photographing or video recording of the surgery to be performed for scientific, medical or educational purposes, provided that the images do not reveal my identity.

13. Consent Verification

I know the alternative treatment methods and their risks.
I know the risks and side effects of the intervention.
I know the possibility of success and failure.
I know what may happen if I am not treated.
I understand that the procedure to be performed may not carry a guarantee of cure.
I have understood everything that has been told to me.
My doctor has answered all my questions.
My doctor has explained to me what is written here, item by item, in a clear, understandable and explanatory manner that I can comprehend.
I know the meaning of the Informed Consent form.
I have been informed about the approximate cost of the treatment.
I am making my decision of my own free will.
I had enough time before the intervention to obtain a second opinion within a reasonable period.
I have read and understood the content of the Informed Consent form.
All the blanks on this form were filled in before I signed it, and I have received a copy.

Signatures

A) Patient-Specific Conditions

The patient writes in their own handwriting any personal conditions (allergies, medications, previous surgeries, etc.). If there are none, writing "NONE" is sufficient.

B) Handwritten Declaration

The patient writes the following sentence in their own handwriting:

"I have read this form carefully, I have been informed about CONGENITAL MIDLINE ANOMALY (MENINGOCELE / MENINGOMYELOCELE), my questions have been answered, and I consent to this procedure of my own free will."

C) Signatures

	Full Name	Signature	Date / Time
Patient			
Patient's Legal Representative / Relative (Relationship: .....)			
Head of Surgical Team, Responsible Specialist	**Dr. Özgür Akşan**		