**INFORMED PATIENT CONSENT FOR KYPHOPLASTY/VERTEBROPLASTY/BIOPSY SURGERY**

**DEFINITION:** The method called biopsy / kyphoplasty /vertebroplasty aims to take a sample (biopsy) by inserting a thick needle into the vertebrae that have collapsed (lost height) due to osteoporosis, tumour, trauma, etc., to inject bone cement after excavating the tumour and to restore height or strength to the fracture. Although the risk and complications of this procedure are low, there may be special complications such as leakage of the cement due to needle placement and bone cement injection.

**Method**: Under local or general anaesthesia under operating theatre conditions, a thick needle is inserted into the vertebrae to take a sample (biopsy), bone cement is given and the fracture is tried to regain height. Sometimes, due to the location of the tumour or fracture, the pedicle where the cannula will enter is found and cement is injected under microscope with open surgery.

**Benefits of Surgery**: Improving the current complaint and clinic, trying to prevent further deterioration

**Possible Consequences of Failure to Perform the Operation**: The current clinical condition may persist, worsen, or the patient may become paralysed.

**Alternatives**:

This is the only option when it comes to vertebral tumours or when the fracture is dangerous. This procedure may sometimes involve the use of instrumentation such as screws or plate rods. Your doctor will decide and inform you.

**Risks of Surgery:**

**General risks**:

**Bleeding**: There is a risk of bleeding during or after the operation, which may be severe. In case of bleeding, additional treatment or blood transfusion may be required. The medication used may also increase the risk of bleeding.

**Blood Clot Formation**: Blood clots can form after any type of surgery. Clots that form in the bleeding area can block blood flow and cause complications such as pain, oedema, inflammation or tissue damage.

**Spinal Cord Injury**: Though very rare, paralysis can occur due to spinal cord injury during surgery. Paralysis may be permanent.

**Cardiac Complications**: The operation has a low risk of causing irregular heart rhythm and heart attack.

**Death:** Although rare, there is a risk of death during or after the operation due to the operation and complications. It has been reported due to cement leakage.

**Unsuccessful surgery**: There is a risk that pain, drowsiness, loss of muscle strength or other complaints may not be relieved after spinal surgery.

**Increased Pain Complaint**: In rare cases, pain complaints may increase after surgery.

**Infection**: Infection can occur at the skin incision site, at the operation site or even in the bone at the operation site. Risks associated with infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (pus accumulation).

**Nerve root injury**: Nerve root injury can cause pain in the leg, weakness in the involved muscle groups, and sensory disturbances in the involved dermatomes.

**Risk of Cerebrospinal Fluid Leakage**: After the operation, a leakage of cerebrospinal fluid from the wound to the external environment may occur. This may require a spinal catheter or additional intervention to repair the same wound site.

**Recurrence**: After surgery, symptoms may reappear and additional surgery may be required.

**Respiratory Distress**: After the operation, respiratory distress or pneumonia, which is usually temporary, may occur. Pulmonary embolism (blockage of the blood vessels of the lungs) may occur.

**Ventilator and Intensive Care**: Depending on the complications that may develop in the patient, ventilator support and intensive care unit monitoring may be required.

**Complications that may appear specific to biopsy/vertebroplasty/kyphoplasty**:

• All structures near the needle's entry path are at risk. These include the spinal cord, nerve roots, blood vessels, oesophagus, lungs and other abdominal organs.

• During bone cement injection, the spinal cord or nerve roots may be compressed due to protrusion of the cement, which may cause temporary or permanent nerve damage.

• Fat clots can travel into the blood vessels and then into the lungs.

• There may be prolonged bleeding.

• There may be air stasis between the lung membranes and respiratory distress.

• Spinal fluid leakage and infection may occur.

• Rib fractures may occur.

• It may result in death.

**General risks and complications:**

**Allergic Reactions**: In rare cases, allergic reactions to the patches, suture material or topical preparations used have been reported. More serious systemic reactions may occur with medications used during or prescribed after the surgical procedure. Allergic reactions may require additional treatment.

**Anaesthesia**: Both local and general anaesthesia carry risks. All surgical anaesthesia and sedation procedures have the potential for complications ranging from minor to fatal.

**Unsatisfactory Results**: You may be disappointed with the outcome of your surgical procedure. You may develop unsatisfactory surgical scarring. There may be pain following surgery.

Additional surgical intervention may be required to correct the results.

All of the above-mentioned risks are significantly increased in patients who smoke, are overweight, have diabetes, high blood pressure and previous heart disease.

**Special Circumstances**:

**Allergy / Medicines Used**: I informed my doctor about all my known allergies. I also informed my doctor about the prescription drugs, over-the-counter drugs, herbal medicines, dietary additives, illegal drugs, alcohol and drugs/sedatives I use. The effects of the use of these substances before and after surgery were explained to me by my doctor and recommendations were made.

**Tobacco and Tobacco Products**: I have been told that smoking tobacco and tobacco products (cigarettes, hookahs, cigars, pipes, etc.) before or after my operation may prolong my recovery. I know that if I use any of these substances I am at greater risk of wound healing problems.

**Consent Verification**: MY DOCTOR GAVE ME ENOUGH INFORMATION BEFORE HOSPITALISATION.

I have read and understood the contents of the informed consent form and my doctor has answered all my questions. I decide to be treated of my own free will. I know that I have the right to refuse this intervention or to withdraw at any time.

**Estimated Duration of the Procedure**: 30 min - 1 hour.

**Important features of the medicines to be used:** During my stay in the hospital, I received information about the important features of the medicines to be used for diagnosis and treatment (what they are used for, their benefits, side effects, how to use them).

**Lifestyle Recommendations Critical to the Patient's Health:** I received information about what I need to do for my lifestyle after my treatment/operation (diet, bathing, medication, mobility and/or restriction).

**How to Access Medical Assistance in the Same Subject When Necessary**: I received information on how to access medical assistance (own physician, another physician, the clinic where he/she is being treated and, in case of emergency, 112) if necessary.

**Phone Numbers You Can Contact Us:** Hospital Tel: 0 322 454 44 30

You can consult your physician for more detailed information about the procedures to be performed.

**Authorisation for the treatment of unpredictable conditions:** I agree to the implementation of the above-mentioned intervention and other additional interventions that may be required as a medical necessity during the intervention. I will not take legal action due to complications that develop due to surgery, provided that they are not excluded from the acceptable complications specific to my disease and treatment mentioned above.

The patient must write in his/her own handwriting **I HAVE READ, HAVE UNDERSTOOD, ACCEPT**.

**Patient or legally responsible person:**

Name and surname:

T.R. Identity no:

Protocol no:

Signature :

**Witness :**

Name and surname:

Relativeness to patient:

Signature:

**The part to be filled in by the physician after the patient's consent is completed:**

I confirm that the procedure described above, the risks, possible complications and expected results have been explained by me to the patient or his/her legal representative prior to the patient's or his/her authorisation.

**Treating physician:**

Seal-Signature Date:\_\_\_\_/\_\_\_\_/\_\_\_\_ Time: .....:…..

|  |  |  |
| --- | --- | --- |
| **PREPARED BY** | **CONTROLLED BY** | **APPROVED BY** |
| NEUROSURGERY AND NEUROSURGERY SPECIALIST | QUALITY MANAGEMENT DIRECTOR | CHIEF PHYSICIAN |