GOVERNMENT OF WEST BENGAL
DEPARTMENT OF HEALTH & FAMILY WELFARE
SWASTHYA BHABAN, SALT LAKE, KOLKATA

Memo No. M/1235/A Date: 25.06.2021

NOTIFICATION

On the backdrop of an increasing incidence of rhino-orbito-cerebral Mucormycosis needing debridement surgeries over the head and facial region involving important organs amidst COVID-19 pandemic situation, a Standard Informed Consent Form for such surgeries prepared by an Expert Committee is enclosed herewith, to be followed in the Government Institutions under WBHS and WBMES.

This has got clinical and Medicolegal implications in the treatment of Mucormycosis.

All concerned are hereby informed.

25/6/21
Director of Health Service
Department of Health & F.W.

Director of Health Services
Government of West Bengal

25/06/2021
Director of Medical Education
Department of Health & F.W.

Director of Medical Education
Government of West Bengal
Swasthya Bhavan
Kolkata-700091

Government of West Bengal
Department of Health and Family Welfare
Swasthya Bhavan saltlake-91

INFORMED WRITTEN CONSENT FORM FOR RHINO ORBITO CEREBRAL MUCORMYCOSIS

HOSPITAL REG NO:

NAME OF HOSPITAL:

AGE:

NAME OF PATIENT:

ADDRESS:

Mucormycosis is a potentially lethal, angio-invasive fungal infection involving nose, paranasal sinuses, eye, orbit and brain. It is a rapidly progressive disease and turns fatal very easily.

The disease has involved:

1. Nose ☐
2. Oral Cavity including hard palate ☐
3. Para-nasal sinuses ☐
4. Orbit and Eye ☐
5. Brain ☐
6. All of the above ☐

The following interventional procedure will be done: Please Tick

1. Intra-orbital injection of Amphotericin B (RE/LE) ☐
2. Orbital exploration &/ Debulking of Necrotic Tissue (RE/LE) ☐
3. Endoscopic exploration of nose and Para-nasal sinuses (Right Side/ Left side/ Bilateral) ☐
4. Partial Maxillectomy (Right Side/ Left side/ Bilateral) ☐
5. Total Maxillectomy (Right Side/ Left side/ Bilateral) ☐
6. Partial maxillectomy with Zygoma debridement (Right Side/ Left side/ Bilateral) ☐
7. Total Maxillectomy with Zygoma debridement (Right Side/ Left side/ Bilateral) ☐
8. Lid Sparing Orbital Exenteration (RE/LE/ BE) ☐
9. Periorbita Sparing Exenteration (RE/LE/BE) ☐
10. Lid and Perorbita Sparing Exenteration (RE/LE/BE) ☐
11. Radical Exenteration involving Lid and Periorbita (RE/LE/BE) ☐
12. Any Other surgical Procedure: Please Specify

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NATURE OF THE PROCEDURE WITH EXPECTED OUTCOME AND LIKELIHOOD OF SUCCESS:

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RISKS OF THE PROCEDURE

There are risks and complications with this procedure. They include but are not limited to the following:

I. GENERAL RISKS:

a. Bleeding could occur and may require a return to the operating room, especially if the Patient is on blood thinning drugs.
b. Infection can occur, requiring antibiotics and further treatment.
c. Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis (DVT).
d. Cardiac arrest and death as a result of this procedure is rarely possible.

II. SPECIFIC RISKS:

a. Bleeding. This may occur either at the time of surgery or in the first few weeks after surgery. Excessive Bleeding at the time of surgery may be due to injury to some major blood vessel and may even require termination of the procedure and nasal packing. Injury to some major blood vessel can even cause Orbital Hematoma. Bleeding after surgery may require packing of the nose under local anesthesia or may require another operation to stop the bleeding. A blood transfusion may be necessary depending on the amount of blood lost.
b. Eye injury-Injury can be caused to extra-ocular eye muscles. This may lead to bruising or swelling around the eye. Rarely, permanent damage causing double vision or partial or complete loss of vision can occur.
c. Infection of the nose and sinuses. Usually temporary but will require antibiotic therapy
d. CSF leak, Meningitis, Brain abscess may occur if there is damage to the Brain during surgery
e. Damage to the Nasolacrimal duct which can cause tearing of the eye.
f. Perforation in septal wall and Crusting of the nasal cavity.
g. Allergic reaction to medications
h. Cardiac arrest and Death as a result of this procedure is rarely possible.
i. After Exenteration, there can be discharging sinuses and disfigurement of face and orbital region in recent or remote future.

j. After Exenteration, the patient will not see from that eye.
k. After intra-orbital or endoscopic administration of Amphotericin B there may be allergic or anaphylactic reaction to the drug.

III. SPECIFIC RISKS IF ANY FOR THIS PARTICULAR PATIENT:

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DECLARATION OF CONSENT

I acknowledge that the treating team of Doctors has given me through information about the disease and the intervention proposed to be performed on me / my patient. I acknowledge the following facts:

1. My medical condition- I/ My ..... Is suffering from Mucormycosis which is a life threatening invasive fungal infection of the Nose and Paranasal sinuses and can extend to palate, Orbit and even Brain.
2. The proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
3. The anesthetic required for this procedure. I understand the risks of anesthesia explained to me by doctor and that also includes the risks specific to me.
4. There may be Unavailability of necessary Anti-fungal drugs like Amphotericin B and Posaconazole during the treatment procedure at anytime.
5. The Antifungal Drugs are potentially toxic and may cause serious adverse reactyion which may be life threatening.
6. My prognosis, and risks of not having the procedure. If I/my patient ..... do not undergo this surgery the fungal infection will rapidly spread even within hours in some cases to the adjacent structures like Orbit and Brain and may cause either blindness or even death.
7. There are many chances of recurrence of surgery which might need further medical or surgical management again.
8. Facial cosmetic disfigurement can occur secondary to surgery which might require further prosthetic surgery.
9. The procedure may include a blood transfusion and tracheostomy if required.
10. I have been explained that excessive bleeding, infection, cardiac arrest, pulmonary embolism, and complications like this can arise suddenly and unexpectedly while undergoing operative procedure or anesthesia.
11. I give consent for any change in anesthesia or surgery at the time of surgery.
12. During surgery suspected body tissues could be removed for histopathological examination.
13. I have been made aware that after the above operation and anesthesia some complication may arise, and I believe that to avoid such complications if any appropriate care is needed it shall be taken by the surgeon and anesthetist or any other doctor suggested by them.
14. That there is an ICU in the hospital and treating Doctor will shift patient there in case of any complication and take appropriate care/ That there is no ICU in this hospital but this hospital has a tie up with ..... Hospital which has ICU set up and patient will be shifted there in case of any complication so that appropriate care can be taken of.
15. I have been explained that after surgery I might need to take some medications for a particular period of time as per my medical condition and as per prescribed by doctors. After surgery I will have to regularly follow up with my doctor as per his orders.
16. During my stay in hospital all aseptic precautions will be taken by the hospital but still I have chances of acquiring any kind of infection including Covid 19.

17. I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedures and its risks and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
18. I understand I have the right to change my mind at any time, including after I have signed this form but preferably following a discussion with my doctor.
19. I understand that images or video footages may be recorded as a part of or during my procedure.
20. I accept that medicine is not an exact science and understand that no guarantees can be given to the results even after complete removal of the disease and understand these limitations.
21. I have read the above writing; the above writing has been read out to me and explained to me in ..... Language by interpreter.....which I understand.
22. I request
DR.....
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..... and his/her team of Doctors To perform the above mentioned procedure.

The person giving consent has/ does not have capacity and competence to give consent.
I,..... Related to the patient as
..... the undersigned give consent willingly for myself/ my patient for the required procedure with sound mental state without any Coercion, Undue Influence, Fraud, Misrepresentation or Mistake of Facts. DIAGNOSIS: SINONASAL/ ORBITAL/CEREBRAL MUCORMYCOSIS.

DECLARATION BY DOCTORS

I declare that I have explained the nature and consequences of the procedure to be performed, and discussed the risks that particularly concern the patient. I have given the patient an opportunity to ask questions and I have answered these.

For EXENTERATION: I agree that the extent and involvement of the disease in orbit requires EXENTERATION salvaging the eye to save the life of the patient:

1. Dr.....
2. Dr.....
3. Dr .....

Doctor:

1. Name:
2. Signature:
3. Date:

Witness 1:

1. Name:
2. Signature:
3. Date:

Patient/ Authorized Representative of the patient:

1. Name:
2. Signature:
3. Date:

Witness 2:

1. Name:
2. Signature:
3. Date: