



GOVERNMENT OF KERALA



Abstract

Health & Family Welfare Department - Guidelines for the Brain Death Certification - Orders issued.

HEALTH & FAMILY WELFARE (B) DEPARTMENT

G.O.(Ms)No.7/2020/H&FWD Dated,Thiruvananthapuram, 19/01/2020

- Read:-
1. G.O (Rt) No.3060/2018/H&FWD dated 06.10.2018
 2. Letter dated 16.02.2019 from Dr. Thomas Iype, Professor & Head, Department of Neurology, Government Medical College, Thiruvananthapuram.
 3. Letter No.CA No.10/2019/SPL dated 24.05.2019 from the Special Officer, Directorate of Medical Education.
 4. Letter No.615/2019/KNOS dated 05.11.2019 from Dr. Noble Gracious, Nodal Officer, Kerala Network for Organ Sharing.

ORDER

In order to streamline the procedure for declaration of brain stem death, uniform procedure has to be laid down. The determination of brain stem death should be decided based on a standard clinical practice which is adapted world over as per the present medical and scientific knowledge. It is also imperative to do proper capacity building among medical practitioners and generate awareness among people on brain stem death and its certification procedure.

2. Section 2(1)(b) of The Registration of Births and Deaths Act, 1969 defines "death" as the "permanent disappearance of all evidence of life at any time after live-birth has taken place." There is no specific reference to the cessation of cardiac or respiratory functions in this definition. It is clear from the scheme of the Act that the main purpose of the Act is to maintain and collect information about births and deaths, rather than prescribing how death should be determined. The determination of death is a medical function, which is reflected in the provisions of the Act. The Rules framed under the Act specify the format for the medical certificate of the cause of death (Form No.4 under the Kerala Registration of Births and Deaths Rules, 1999), which lays an emphasis on the kinds of information that are to be documented, rather than prescribing the method that medical practitioners should adopt to reach a determination of death. The form requires information about the immediate cause of death as well as other significant conditions of death.

3. In the section on "Cause of Death", the directions for completing Form

No.7 state that medical practitioners must first enter the immediate cause of death. It is then clarified that: "This does not mean the mode of dying, e.g., heart failure, respiratory failure etc." The use of the term "etc" in this context is of significance. It suggests that there may be other modes of dying apart from heart failure or respiratory failure. One of these modes is brain stem death and therefore, brain-stem death is also considered death under the Registration of Births and Deaths Act, 1969.

4. The WHO, Global Glossary of Terms and Definitions on Donation and Transplantation, 2009, defines brain-stem death as: "Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time."

5. In Indian law on the determination of brain-stem death, it is clear that declaration of brain-stem death means, declaring a person to be dead - both clinically and legally. Allowing the brain-dead to continue on ventilators may lead to potential harms which include mistreatment of the dead, deprivation of dignity, provision of false hope with resultant distrust, prolongation of the grieving process, undermining the professional responsibility of the physician to achieve a timely and accurate diagnosis, and an anticipated societal harm arising from a negotiated and inconsistent standard of death determination.

6. Considering all these aspects, as per the Government Order read above, an Expert Committee was constituted for developing parameters for Brain Death Certification so as to remove the ambiguities in the minds of health care providers as well as the public, thereby making the process of declaration of death transparent. The Committee has submitted its report as per the letter read as 2nd paper above. A Workshop was conducted on 14.05.2019 participating experts in various specialities including national experts to discuss the report submitted by the Expert Committee. Another meeting was also conducted with academic, administrative and legal experts on 16.10.2019. By consolidating the opinion received during the workshop and the meeting, the Nodal Officer, Kerala Network for Organ Sharing, as per the letter read as 4th paper above, has submitted a proposal for issuing guidelines for Brain Stem Death Certification.

7. Government have examined the matter in detail and are pleased to issue the following guidelines for Brain Stem Death Certification with the objective of ensuring appropriate level of care to patients, to perform standard clinical procedure to follow for declaration of death by brain stem death criterion and to ensure dignity of the deceased.

- i. The clinical evidence of an acute central nervous system catastrophe which is compatible with a clinical diagnosis of brain death should be established before subjecting a person to further tests for evaluating brain stem death.
- ii. The medical practitioners should have a conversation with the near relatives/caregiver regarding the medical status and prognosis of the patient in whom brain stem death testing including apnoea test is being considered

for confirmation of brain stem death diagnosis.

- iii. The assessment of brain stem reflexes should be done using a series of tests, which are to be repeated after an interval of six hours by a panel of four doctors, including a doctor empanelled by the Appropriate Authority. One doctor in the panel has to perform the test and it is mandatory that other panel members have to witness and interpret these tests.
- iv. The Apnoea test is the last brain stem reflex test to be performed, and that too, only if all other tests confirm the absence of other brain stem reflexes.
- v. All the prescribed tests are required to be performed twice by the panel of doctors with the minimum interval of 6 hours between the tests "to ensure that there has been no observer error" and persistence of the clinical state can be documented with absolute degree of certainty. It is to be noted that the diagnosis is based only on the clinical examination.
- vi. A neurophysiological or imaging study to prove the absence of electrical activity or blood flow should be carried out if the treating team or panel of doctors who are certifying, are in doubt in the diagnosis of brain stem death.
- vii. After the completion of two consistent examinations by the panel of medical experts, if criteria for brain stem death are met, the committee must declare the patient dead and note the date and time of the declaration in the medical record.
- viii. The time of death is the time the arterial pCO₂ reached the target value in the second apnoea test.
- ix. The family member/caregiver should be provided with brain stem death confirmation report signed by all the four members of the brain stem death certifying team.
- x. All treatment including Cardiorespiratory support must be discontinued once brain stem death is pronounced.

8. The prescription of the tests to be followed in sequence to ascertain the absence of brain-stem functions are elaborately enumerated in the Annexures attached to this order.

(By order of the Governor)

RAJAN NAMDEV KHOBRADE
PRINCIPAL SECRETARY

The Advocate General, Ernakulam (with C/L).
The Director of Medical Education, Thiruvananthapuram.
The Director of Health Services, Thiruvananthapuram
The Principals/Superintendents of all Government Medical Colleges
(Through Director of Medical Education)
Dr. Noble Gracious, Nodal Officer, Kerala Network for Organ Sharing, Super

Speciality Block, Government Medical College, Thiruvananthapuram
The Principal Accountant General (Audit), Kerala, Thiruvananthapuram
The Accountant General (A&E), Kerala, Thiruvananthapuram.
The Information & Public Relations Department (Web & New Media)
Stock File/Office Copy

Copy to:- The P.S to Minister (Health, Social Justice and Women & Child
Development)

The P.S to Principal Secretary, Health & Family Welfare Department

Forwarded/By order
Signature valid

Digitally signed by ANIL KUMAR D
Date: 2020.01.20 17:49:32 IST
Reason: Approved

Section Officer

ANNEXURE 1

**PROCEDURE TO BE FOLLOWED FOR BRAIN STEM DEATH
CONFIRMATION****STEP 1 - PREREQUISITE FOR BRAIN STEM DEATH
CONFIRMATION**

The most important step before subjecting a patient for brain stem death confirmation is to rule out any reversible causes of coma.

1. Establish the irreversible and proximate cause of coma. History, clinical and/or neuroimaging evidence of an acute central nervous system (CNS) catastrophe that is compatible with the clinical diagnosis of brain stem death such as severe traumatic head injury, aneurysmal subarachnoid haemorrhage, severe ischemic stroke, hypoxic-ischemic brain injury etc. should be present. The patient should be in apnoeic coma that is unresponsive on a ventilator, due to a cause which is irremediable. Irremediable means that no treatment nor any therapeutic endeavours may be reasonably expected to change the patient's condition even after an adequate period of observation.
2. Exclusion of reversible cause of coma:- There is no urgency to make a diagnosis of brain stem death and all the confounding factors have to be excluded by sufficient means.

a. Intoxication

Acute intoxication (alcohol and other drugs) is the commonest cause that needs to be excluded. If intoxication is suspected, it is important to keep in mind the approximate plasma half-lives of various coma-producing drugs and that brain concentrations may lag significantly behind blood concentrations. When toxicological facilities are available, the facility may be utilized for screening drug levels of the suspected intoxicant which may interfere with the brain stem death confirmation.

b. Relaxants (Neuromuscular blocking agents)

Drug-induced residual neuromuscular junction blockade can mask brain stem reflexes and produce apnoea. This must be excluded if neuromuscular blocking agents have been used or suspected to have been used. If residual neuromuscular blockade should be tested, it should be done with the peripheral nerve stimulator. (Annexure- 2)

c. Depressant Drugs

The length of time between discontinuation of depressant drugs and undertaking brain-stem testing depends on several factors including total dose, duration of exposure to the drug, the underlying kidney and liver function and

the ability to measure the drug concentrations in blood. Hence it is essential that the recent history of the drugs ingested or administered be carefully reviewed before proceeding with brain stem death confirmation.

d. Primary Hypothermia

Temperatures between 32-34°C are occasionally associated with an impaired level of consciousness but brain-stem reflexes tend to be lost if the temperature falls below 28°C. These deficits are potentially reversible. Hence it is recommended the core temperature should be > 32°C at the time of brain stem death diagnosis.

Core temperature:

Age > 18 years - core temperature >36° C

Age > 1 year to 18 years - core temperature 36° C

e. Hypovolemic shock

Systolic blood pressure must be > 90 mm HG in age >18 years.

f. Endocrine & metabolic disorders:

It is recognised that metabolic and endocrine disturbances (e.g. hypernatremia, diabetes insipidus) are likely accompaniments of death as a result of the cessation of brain-stem function. It is important to emphasise that these may be the effect rather than the cause of cessation of brain stem function and do not preclude the diagnosis of death by neurological testing of brain-stem reflexes. Furthermore it may be detrimental to correct such abnormalities too rapidly and to delay testing of brain-stem reflexes, simply because of the need for strict adherence to attain a predetermined blood electrolyte concentration.

STEP 2—ASSESSMENT OF BRAIN STEM REFLEXES

2.1. Two sets of tests are required to be done, the minimum time interval between the first and second testing will be 6 hours in adults. In the case of children of age more than 30 days to 18 years, minimum interval should be 12 hours.

2.2. It is mandatory that two series of tests are performed for brain stem death diagnosis.

- i. Pupillary size (Both sides to be tested)
- ii. Pupillary light reflexes (The pupils are fixed and do not respond to sharp changes in the intensity of incident light) (Both sides to be tested)
- iii. Dolls head eye movements or Oculo-cephalic reflex ("absence of movements of the eyes in relation to head movement). Both sides have to be tested NB:- These tests cannot be performed in persons with cervical spine injury.
- iv. Corneal-conjunctival reflex (There should be no corneal reflex - care

should be taken to avoid damage to the cornea). Both sides have to be tested separately.

- v. Motor responses to central and peripheral noxious stimuli (No motor response can be elicited to supra orbital or peripheral (nail bed) pressure in brain stem dead patients). Both sides to be tested.
- vi. Cough and Gag reflex (There is no cough reflex response to tracheal stimulation by a suction catheter placed down the trachea to the carina, or gag response to stimulation of the posterior pharynx using a spatula)
- vii. Eye movements on caloric testing (No eye movements are seen during or following the slow injection of at least 30-50 ml of ice-cold water over 30 seconds into each external auditory meatus in turn. Clear access to the tympanic membrane must be established by direct inspection and the head should be at 30° to the horizontal plane unless this positioning is contraindicated by the presence of an unstable spinal injury).

Procedure for the cold caloric test:-

The head end of the bed is elevated to 30 degrees.

30 to 50 ml of ice-cold water is injected slowly over 30 seconds into the ear.

Once the water is injected, both the eyes are held open to observe the ocular movement.

In patients with an intact brain stem, a slow movement of the patients eyes to the side of the ice-water irrigation, followed by a rapid corrective movement of the eyes to the opposite side is noted.

The second ear should be tested after a gap of 5 minutes.

STEP 3- APNOEA TEST

The process for testing the response of respiratory centre of the brain stem to carbon dioxide stimulus (Apnoea Test). This should be the last brain stem function to be tested and should not be performed if any of the preceding tests confirm the presence of brain stem reflex. Correction of hypotension, metabolic acidosis (acceptable pH of 7.2) and pre-oxygenation is mandatory before apnoea testing

3.1. Preparation for apnoea test

- i. The adult patient should have a temperature of more than 36 degree centigrade and adequate circulating fluid volume with Systolic blood pressure of > 90mm of Hg.
- ii. The first apnoea test should be performed only after a minimum of four hours of apnoeic coma associated with the absence of brain stem reflexes. This refers to the clinical examination done and not to Step 2 of the brain stem death tests. In the case of Anoxic/hypoxic brain damage, this period should be extended to 12 hours or more.
- iii. Ventilator manipulation is performed to raise the PaCO₂ => 40 mmHg.

- iv. The patient should be preoxygenated with 100% Oxygen for 15 minutes, while still on the ventilator, before the apnoea test.
- v. A blood gas test should be done to determine the adequacy of the baseline before the test. SP02 should be monitored during Apnoea test
- vi. Place the patient on 100% Oxygen through a tracheal catheter with the tip towards the end of the tube with a continuous 6L/min O2 flow
- vii. The patient is kept off the ventilator for a variable period (usually 5 to 8 minutes) to allow the PaCO₂ to rise > 60mm Hg or > 20mmHg over baseline. During this time, the patient's chest and abdomen is exposed and observed for respiratory movements
- viii. The brain stem certifying expert committee should present during step 1, 2 and 3 for recording the time of death if apnoea test is positive.

Test interpretations:

- a. Positive Test - implying apnoea despite adequate stimulation
The patient remains apnoeic, without respiratory movements.
PaCO₂ is >60mm Hg or >20 mmHg from baseline.
- b. Negative test - Implying apnoea is not present
Respiratory efforts noted at any time during the test
- c. Indeterminate test
PaCO₂ <60 mmHg or, there is less than 20mm Hg increase over baseline.

Indeterminate tests can either be repeated or, another confirmatory test as prescribed in Annexure5 may be utilized.

Apnoea test should be aborted if the patient develops hypotension, desaturation or significant cardiac arrhythmias. (use of CPAP valve to counter desaturation, may be useful here)

These norms will vary for patients less than 12 years and patients with major chest trauma.

d. When to abandon the certification process: Rather than ordering ancillary tests, physicians may decide not to proceed with the declaration of brain stem death if clinical findings are unreliable.

ANNEXURE 2

TESTS TO EXCLUDE NEURO MUSCULAR BLOCKING AGENTS

PERIPHERAL NERVE STIMULATION TEST

Apply train of four stimuli (20 mA, 0.2-millisecond Jules, 500 milliseconds apart on Ulnar Nerve at the wrist and look for movements of adductor pollicis muscle (medial adduction movement of thumb across the palm).

DESCRIPTION

- i. A peripheral nerve is stimulated by an electrical signal
- ii. Twitch = muscle response to the stimulus
- iii. The ulnar nerve is most commonly used; alternatives include posterior tibial, facial and peroneal nerve
- iv. ECG dots (ensure good skin contact and current flow)
- v. Electrodes (black and red)
- vi. Nerve stimulator console

METHOD OF USE

Ulnar nerve:

- > ECG dots placed
 - i. First dot on the palmar aspect of the wrist 1-2 cm proximal to the wrist
 - ii. Second dot in the same line 3 cm proximal to the first dot.
- > Electrodes attached
 - i. Black (negative) electrode is attached to dot closest to hand (place as close to nerve as possible).
 - ii. Red (positive) attached to the proximal dot (must be in line to minimise nerve-muscle artefact and ensure maximal stimulation).
- > Stimulator is attached
 - i. Voltage is slowly increased starting at 20mA, the voltage should not exceed 60 mA
 - ii. Red pulse light indicates voltage conduction.
 - iii. Observe twitching of adductor pollicis (medial adduction of the thumb across the palm)

Interpretation:- Presence of twitch indicates that there is no residual muscle paralysis that is producing a falsely absent brain stem reflex.

ANNEXURE 3

CHECKLIST FOR DETERMINATION OF BRAIN DEATH PRE-REQUISITRES (all must be checked)**A. Pre-requisites for brain stem death testing**

- i. Coma, irreversible and cause known.
- ii. Neuroimaging explains coma.
- iii. CNS depressant drug effect absent (if indicated toxicology screen; if barbiturates given, serum level <10 mcg/ml).
- iv. No evidence of residual paralytics (electrical stimulation if paralytics used).
- v. Absence of severe acid-base, electrolyte, endocrine abnormality.
- vi. Normothermia or mild hypothermia (core temperature >35°C).
- vii. Systolic blood pressure >90 mm Hg.
- viii. No spontaneous respirations.

B. Assessment of brain stem reflexes

- i. Pupils nonreactive to bright light.
- ii. Comeal reflex absent.
- iii. Oculocephalic reflex absent (tested only if C-spine integrity ensured).
- iv. Oculovestibular reflex absent.
- v. No facial movement to noxious stimuli at supraorbital nerve, temporomandibular joint.
- vi. Gag reflex absent.
- vii. Cough reflex absent to tracheal suctioning.
- viii. Absence of motor response to noxious stimuli in all four limbs (spinally mediated reflexes are permissible).

C. Apnoea testing

- i. Patient is hemodynamically stable.

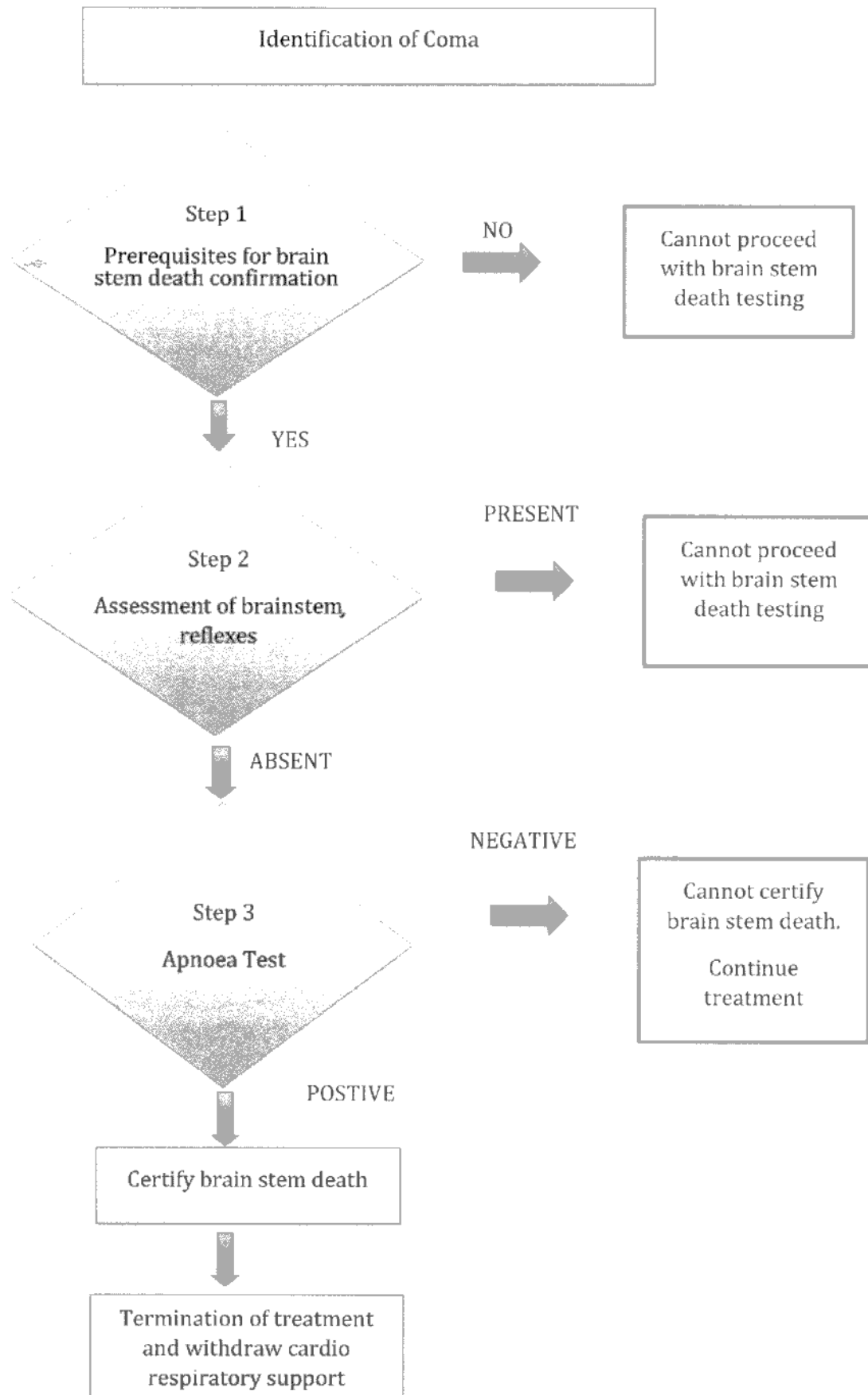
- ii. Ventilator adjusted to provide normocarbica (PaCO₂ 35-45 mm Hg).
- iii. Patient preoxygenated with 100% FiO₂ for >10 minutes to PaO₂ >200 mm Hg.
- iv. Patient well-oxygenated with a positive end-expiratory pressure (PEEP) of 5 cm of water.
- v. Provide oxygen via a suction catheter to the level of the carina at 6 L/min or attach
- vi. T-piece with continuous positive airway pressure (CPAP) at 10 cm H₂O.
- vii. Disconnect ventilator.
- viii. Spontaneous respirations absent.
- ix. Arterial blood gas drawn at 8-10 minutes, patient reconnected to ventilator.
- x. PCO₂ >60 mm Hg, or 20 mm Hg rise from normal baseline value.

*Sequence to be followed

Step B to be considered if all the requirements of Step A are fulfilled.

Step C should be performed if both A and B are consistent with the diagnosis of brain stem death.

ANNEXURE 4
BRAIN STEM DEATH CERTIFYING ALGORITHM



ANNEXURE 5

ANCILLARY TESTS

(To be considered in the following situations)

- I. SPINAL REFLEXES - When brain stem death testing is performed, very infrequently, the patient may move an extremity in response to noxious stimulation (Lazarus Phenomenon). If there is any question about the significance of movements or other responses, any one of the objective confirmatory tests should be performed-CT angiogram, EEG, Transcranial Doppler, cerebral scintigraphy, Nuclear brain scanning, Transcranial Doppler ultrasonography, Cerebral arteriography.
- II. APNOEA TEST- The apnoea test is performed by pre-oxygenating the patient with 100% oxygen and then allowing the patient's PCO₂ to rise to 60 mmHg or greater. Occasionally, the apnoea test will not be tolerated by some patients whose cardiopulmonary status is unstable. In these patients brain death cannot be determined on clinical grounds alone. Therefore any one of the objective confirmatory tests may be performed- CT angiogram, EEG, Transcranial Doppler, cerebral scintigraphy, Nuclear brain scanning, Transcranial Doppler ultrasonography, Cerebral arteriography.