

Patient Information Sheet

Title: Role of beta blocker in cerebral salt wasting in the patients with tuberculous meningitis: An open labelled randomized control trial

Tuberculous meningitis is the commonest cause of sub-acute and chronic meningitis in India and occurs in ~0.9% of the patients with tuberculosis. One-third of TBM patients may develop low serum sodium and high urinary output. This has been found to be more commonly because of cerebral salt wasting (CSW). In TBM, there is increased stress and CSW has been attributed to high catecholamine. Betablocker (propranolol) is a drug used for reducing stress and to suppress catecholamine induced injury. Low serum sodium and high urinary output due to CSW may have early correction following adjunctive propranolol treatment. Hyponatremia is an independent risk factor of death in intensive care unit. Early correction of sodium and volume loss may reduce death and improve outcome. Propranolol is a drug used in medical practice for long time. It has a side effect profile including slowing of heart rate and reduction in blood pressure. Your pulse and blood pressure will be monitored closely and in case of such side effects, the drug will be withdrawn. You are selected because you are suffering from TBM with cerebral salt wasting. You will receive salt and normal saline for correction of hyponatremia over and above propranolol. For participation you have to give 5 ml of blood and 2 ml of CSF. Blood will be drawn from antecubital vein under aseptic condition, which is little painful. Cerebrospinal fluid will be done by lumbar puncture using local anesthesia and is essential for the diagnosis of tuberculous meningitis. We will collect 2 ml for our study during that procedure. You will have to give a consent for the use of blood and CSF for further analysis for understanding disease pathophysiology in future. Your participation is voluntary and you can also withdraw your name at any point during the study without giving any reason. Irrespective of whether you participate or not, the standard of care will remain the same. There will be no charges for participating in the study.

You can ask your parent or spouse or friend before signing the consent form.

Your identity will not be revealed and will be kept confidential. The Institutional Ethics Committee has reviewed the study.

By participating you may or may not have an immediate benefit but we will be able to understand your disease better.

Contact for further information

For further information, contact:

Dr. Jayantee Kalita

Professor

Dept. of Neurology, SGPGIMS

Lucknow

Dr. Vinita Agarwal

Member Secretary

Ethics committee,

SGPGI, Lucknow,

0522-2494169

0522-2494918

Thank You for taking part in the study.