양산부산대학교병원
PUSAN NATIONAL UNIVERSITY YANGSAN HOSPITAL

This Informed Consent Form is for men and women who attend Pusan National University Yangsan Hospital, and who we are inviting to participate in research. The title of our research project is "The effect of electromyogram activity on anesthetic depth monitoring : comparison between phase lag entropy and bispectral index".

[Name of Principal Investigator] Tae Kyun Kim
[Name of Organization] Pusan National University Yangsan Hospital
[Name of Sponsor] Inbody CO., LTD
[Name of Proposal and version] 1.0

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Tae Kyun Kim, working for the Pusan National University Yangsan Hospital. We are doing research on bispectral index (BIS) and phase lag entropy (PLE), which is very commonly used in general anesthesia. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

PLE is an index that quantifies the complexity of functional connections occurring between measurement areas of electroencephalogram (EEG). It records the electric activity signal of t he brain via a sensor attached to the scalp, especially forehead, amplifies the measured EEG s ignal via the measurement module, and then processes the data. In this study, we will investig ate whether the measurement method of the depth of anesthesia based on the PLE using phas e lag entropy monitor (PLEM) 100 rather than the BIS algorithm reflects the anesthetic depth well without being affected by the electromyogram (EMG) activity.

Type of Research Intervention

This research will not involve any injection in your arm as well as four follow-up visits to the clinic. We keep the BIS and PLEM 100 on your forehead during anesthetic m onitoring. When you participate in this study, we will use the BIS and PLEM 100 for all parti cipating patients, regardless of test group or control group.

Participant selection

Inclusion criteria

Among adult males and females between the ages of 20 and 60, those who can voluntarily ex press their intention to participate in research, corresponding to the classification of physical status I and II of the American society of anesthesiologists (ASA).

Classification of physical status by ASA

Class I - healthy normal patient

Class II - patients with mild systemic disease but no functional limitation

Exclusion criteria

Patients who have lesions that can affect EEG such as cerebral hemorrhage, cerebral apoplex y and epilepsy and who have disease that can affect EMG such as muscular dystrophy, musc le stiffness, inflammatory muscular lesions, metabolic myopathy, congenital myopathy, myas thenia gravis are excluded from the subject.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital , and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Drug [BIS, PLEM 100]

BIS

BIS introduced the concept of phase angle as well as the frequency and amplitude of electroe ncephalogram. It is closely related to the level of sedation and consciousness by anesthetic dr

ugs and used to monitor the state of consciousness of the patients during general anesthesia.

Classification of awareness state according to the scope of BIS is as follows.
80-100: awake
80-60: light/ moderate sedation
40-60: general anesthesia
20-40: deep hypnotic state
Less than 20: burst suppression
0: flatline EEG

PLEM 100
PLEM 100 is a device that records the electrical activity of the brain generated in the human body. The PLE is a quantitative index of the complexity of the functional connections that oc cur between measurement areas of EEG and can be obtained by calculating the entropy after extracting the phase relationship patterns in the multi-channel EEG signals of the prefrontal and frontal lobes.

The state of consciousness according to the range of the PLE is as follows.
90-100: awake
60-80: light/ moderate sedation
40-60: general anesthesia
20-40: deep hypnotic state
0-20: isoelectric EEG

Procedures and Protocol
Intravenous administration of 2% propofol and remifentanil would be done for total intravenous anesthesia. After intravenous injection of rocuronium 0.6 mg/ kg for muscle relaxation, endotracheal intubation would be performed. Then, anesthesiologist attaches the sensors of BIS and PLEM 100 on the forehead of the patient, and adheres the neuromuscular

monitoring device on the medial side of the wrist and the ipsilateral thumb to continuously monitor the state of consciousness and muscle relaxation before, during and after surgery. Before the end of surgery, the degree of neuromuscular relaxation should be within deep block (TOF count <2) and the concentration of 2% propofol should be adjusted for maintaining BIS between 50 and 60. Reversal of muscle relaxant could be performed by intravenous injection of sugammadex 4 mg/ kg in the case of deep neuromuscular relaxation, and 2 mg / kg in the case of shallow muscle relaxation degree under neuromuscular monitoring. After then, monitor and record the values of BIS, phase lag entropy monitor (PLEM) 100, and neuromuscular monitoring in 1 minute increments for 5 minutes.

Duration

The research takes place over only the day when you experience the surgery. You don't need to come to the clinic after discharge from postanesthsia care unit.

Side Effects

As already mentioned, this procedure can rarely have unwanted effects. Patients rarely experience irritated skin on forehead, but it is enough to observe that because it almost disappears spontaneously. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop procedure. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

By participating in this research, the possibility of complication is very low. Patients rarely experience irritated skin on forehead, but it is enough to observe that because it almost disappears spontaneously.

Benefits

There may not be any benefit for you but your participation is likely to help us find the answer to the research question. Future generations are likely to benefit.

Reimbursements

You will not be given any other money or gifts to take part in this research.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

[Tae Kyun Kim, Pusan National University Yangsan Hospital/ 82-55-360-2129/ anesktk@pusan.ac.kr]
[Hee Young Kim, Pusan National University Yangsan Hospital/ 82-55-360-2129/ yuvi1981@naver.com]

This proposal has been reviewed and approved by [PNUYH IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [PNUYH IRB, Pusan National University Yangsan Hospital, 82-55-360-3854~5.]).

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the research.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and

to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year