

AANSCNS Position Statement Placebo Surgery

Contact(s):

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1. The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) support the conduct of rigorous validation trials to insure that new operative procedures are safe and effective.
2. In certain specific neurological conditions, the use of "placebo surgery" may reduce investigator and patient bias in analyzing treatment outcome and, therefore, increase the likelihood that results of a trial will be interpreted correctly.

Rationale

Major scientific and technological advances in recent years have resulted in new opportunities to apply novel medical and surgical therapies to the treatment of complex neurological diseases. In the interest of public health, it is critical to insure that these new treatment alternatives are safe and effective before they are put into widespread usage.

In most situations, trials in human subjects are necessary to determine the effectiveness or safety of a new drug or procedure. The most reliable trials are those conducted prospectively and in which the treatment in question is compared with either no treatment or an alternative treatment. For new drug therapies, the benchmark clinical investigation involves a placebo or control group, which is blinded to the patient and physician investigators. For trials involving surgical procedures, this type of study is complicated by the fact that the patients and physician both know whether the patient underwent the procedure. In certain types of trials, this knowledge may introduce bias into the analysis of results, particularly when the endpoints are somewhat subjective in nature.

The use of a placebo surgical control group, may in certain situations, reduce this bias. It is clear that increased objectivity in results analysis is desirable and could feasibly protect the public welfare by insuring that an invalid or dangerous procedure not achieve widespread usage following incorrect interpretation of initial results.

Therefore, the AANS and CNS support the use of placebo surgery in clinical trials, but under limited and carefully selected guidelines:

- Each prospective study should be evaluated individually by appropriate federal and/or local institutional oversight committees to determine if a placebo surgery group is necessary to determine accurate results
- The placebo procedure should be as safe as possible and designed so as to properly blind the study and insure accurate analysis of the results
- Patients must be fully informed as to the nature of the study, necessity for the placebo control group, risks of placebo procedure and treatment alternatives