Presidenza del Consiglio dei Ministri

CNB

COMITATO NAZIONALE
PER LA BIOETICA

THE IMPROPER USE OF PLACEBO

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abstract

The opinion makes clear, through examination of some experimental results, that the use of placebo is not necessary if the investigator applies a superiority design to an already approved drug - if it exists - and precautions are taken regarding the high number of patients, the duration of the trial and above all the adoption of parameters for assessment of the therapeutic effects. It is obvious that the comparison with a placebo instead of an active drug in itself favours the new drug seeking approval. In the so-called *add-on* studies a treatment of proven clinical efficacy is sometimes used as a common basis for all patients who receive in addition a new experimental drug or placebo. In many cases, however, the availability of other drugs is deliberately not considered. In the "three-arm studies," the new drug, even if inferior to the reference drug, albeit within accepted limits, must still prove its superiority to placebo. Improper use of placebo in these cases arises from the fact that while placebo does not present any experimental advantages, it forces a group of patients to be deprived of any treatment.

Therefore the NBC emphasises the unethicality of improper use of placebo as it would deprive the patient of a useful drug. In addition, the NBC highlights the role of ethics committees to ensure that commercial interests do not prevail over the right of patients not to be treated with placebo when an effective treatment is already available for a given therapeutic indication.