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Commentry

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Clinicians have not to use trials like drunks do with street lamps

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Commentary

The importance of the statistical analysis of a trial is out of any doubt. But sometimes also Statistics may be an "incorrect" science because it may be subjected to human opinion and manipulation. Recently reports on a prestigious Journal determined the withdrawing from the market of Starch solutions as they are dangerous for the kidney of septic patients [1,2]. The final message was: Starch kills the patient. All these trials were statistically supported and, by definition, their conclusions might be extended to all critically ill patients.

Before withdrawing from the drug trade, why the Scientific Community did not investigate the correct dosage of Starch? Furthermore, the CRISTAL trial showed that the recommended dose of Starch does not kill the critically ill patient more than crystalloid solutions [3].

The CRISTAL study faces us a substantial issue that concerns trials in critically ill patients. A great amount of data from various population with a great risk of biases.

Spinoza said "*Deus sive Natura*" (Ethica More Geometrica Demonstrata): we are still far from deeply understand the Nature and consequently, essential variables could not have been included.

Let us make a contrived example: Starch would be harmful for children affected by Rubella. We may consider it impossible. But, are we sure? Do we know *Deus Natura*so much clearly to exclude it *a priori*? How many other factors should we consider? Age, environment, drugs interaction, timing of care, are only some of which we know, but there may be other variables we do not consider due to ignorance.

Each patient is on his own, with his own problems, his characteristics and his health reserve and any severity illness score may be helpful to stratify his clinical risk but does not reflect his clinical condition, it can only approach it.

How can we evaluate the effects of a fluid on renal function into a population sample receiving different vasoactive drugs, with a different timing, admitted to different ICUs with different care services and different antimicrobial drugs administration with nephrotoxic effect?

Often at the end of a manuscript we can read sentences like … *Further investigations need...* They leave the door opened to the doubt that their conclusions, even supported by statistics, may be inconclusive. We are convinced that more trials will be always necessary. We are persuaded that Medicine has not to be slave of Statistics, both when it is *pro* and *con*. The common sense and clinical experience have yet to play a predominant role. Surely the off-label use of a drug or its overdosing, may be unsafe for a patient. This principle does not need to be demonstrated by the Statistics.

Clinicians have not to use trials like drunks do with street lamps: not to light but to lean against.

Journals must supervise more carefully manuscripts' data like one does with the black box of the aircraft. Even when the Author is a scientist of fame. Doing so, papers earns authority, whatever the prestige and fame of the Author.

References

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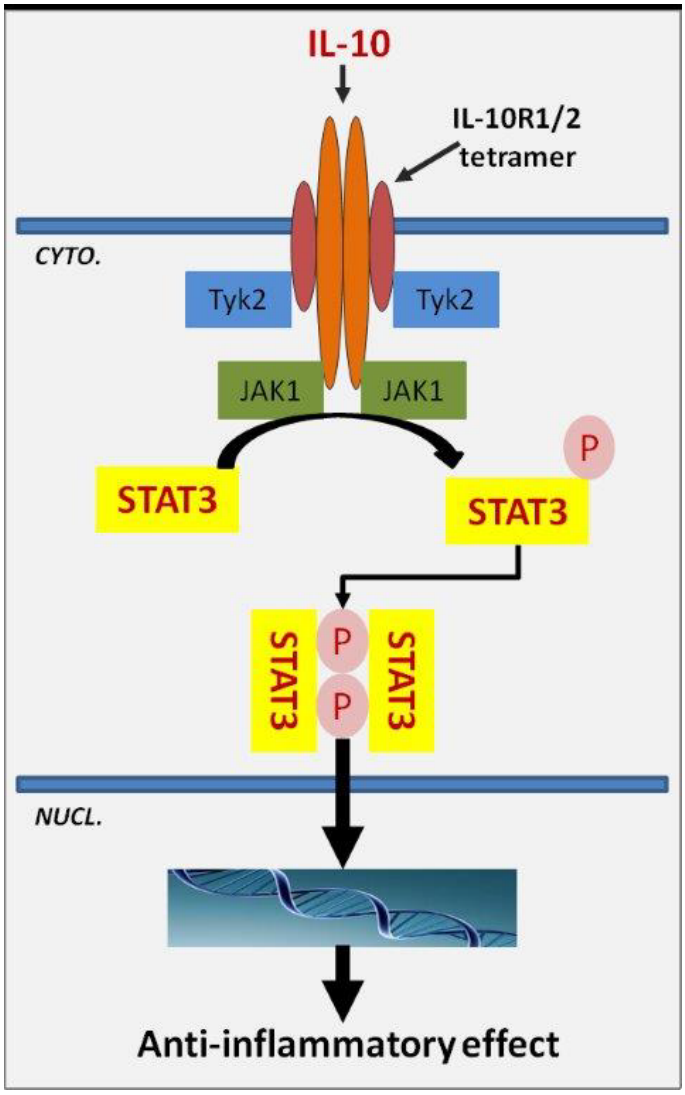

Figure 1. Schematic representation of IL-10 interaction mechanism with the specific receptor. IL-10 binding starts an intracellular signaling pathway involving STAT3 as key translocation nuclear factor which induces the activation of specific gene encoding for anti-inflammatory factors.

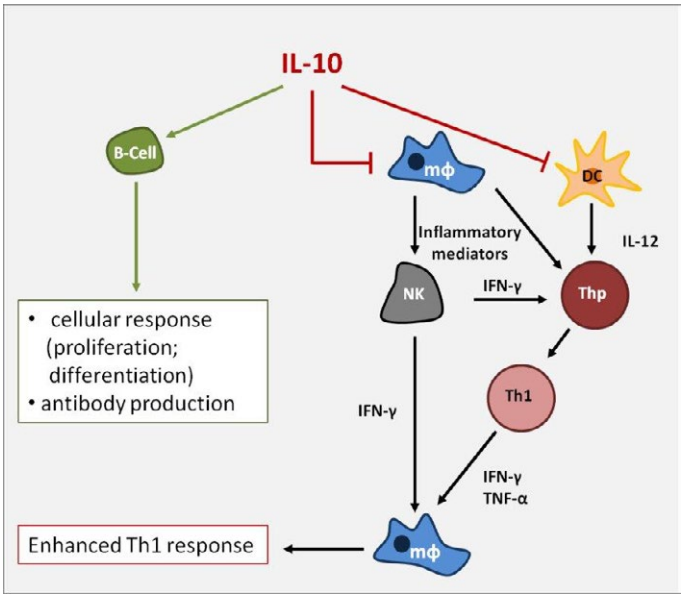

Figure 2. IL-10 is able to modulate the immune reactivity activating the cellular response *via* B-Cells and inhibiting the IFN-γ- mediated Th1 response.