About the AIRTRIP randomised clinical trial: comments on the article by Brucato et al.

Sirs,

There are several important issues about the recent double blind anakinra trial in resistant pericarditis (1).

I. The efficacy of anakinra had been evaluated in this setting before. It has been reported that its use resulted in a complete response in acute pericarditis and reduction of recurrence rate at about 70 to 95% of the patients (2-4). This is now reflected in the power assumptions in the current work with an anticipated response of 80% in the anakinra and 10% in the placebo arms. Given these, one really wonders whether this double blind study was actually necessary. Or was the whole exercise mainly for licensing purposes? If so, we have at hand surely a more and pervasive problem related to our current licensing regulations.

II. Another issue, unfortunately present in the majority of randomised controlled withdrawal trials, is the lack of a control arm in open-label treatment (first) phase. Due to enrichment of a population with responders in the second phase, we cannot assess the treatment effects in a larger heterogenous or unselected population.

III. Apparently the authors screened patients older than 2 and younger than 70 years for eligibility. However, it turned out all enrolled patients were adults (aged >18 years) except a 15-year-old. In brief, this study was conducted in adults by pediatricians. This needs to be highlighted as a limitation.

IV. Colchicine resistance was listed as a main inclusion criteria. However, one does not find its precise definition in the manuscript or in the supplementary data.

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References

