The SIESTA Study

To the Editor:

We have read Magda Heras’ editorial with great interest and are grateful to her for positive comments regarding SIESTA (Systemic Inflammation Evaluation in patients with non-ST segment Elevation Acute Coronary Syndrome) and constructive criticism. There are, however, a number of points raised by Dr. Heras that we wish to elaborate upon. Although not mentioned in the recently published manuscript, the SIESTA study contemplates to carry out an extensive and exhaustive analysis of risk in both obese patients and in those with metabolic syndrome. Body mass index is, indeed, one of the variables that will be analysed in this regard, as included in our original protocol. Furthermore, a substudy of SIESTA will be aimed specifically at assessing the role of diabetes, obesity and metabolic syndrome in relation to the inflammatory response. A further objective of this substudy is to establish whether these variables are independent risk factors in patients with acute coronary syndrome, even when inflammatory markers are included in the analysis.

An ad hoc committee, comprising members of both the Executive and the Ethics Committee, will classify events and decide if, and when, to stop recruitment. Regarding the size of the patient sample, the Steering Committee has decided to incorporate additional centres in order to speed up recruitment and reduce the duration of the study.

Patient data are recorded at the bedside using a personal digital assistant (PDA) and immediately transmitted electronically to the central server for data collection and processing via GPRS. This electronic set-up also allows study participants instant access to the latest entries.

The coordinating centre is St George’s Hospital in London. This centre will not recruit patients but will be responsible for the assessment of biochemical samples and measurement of pro- and anti-inflammatory markers. All biochemical analyses will be performed using state-of-the-art, validated techniques currently in use at the centre.

Statistical analysis, including cost-efficiency analysis will be carried out at St George’s and the latter includes an assessment of the different patient subgroups incorporated to the study, the effects of treatment and the potential financial implications of the routine use of inflammatory markers for the health service.

Contrary to what its name may suggest, SIESTA is an ambitious study that will offer little respite to its investigators. We believe that in conjunction with other Spanish and International clinical studies, SIESTA will represent a major contribution to both the understanding of acute coronary syndromes and patient management.

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REFERENCES