20.06.2011 - Protocol addendum:

Project: Performance of the Ankylosing Spondylitis Disease Activity Score (ASDAS) in patients under biological therapies

Title of the addendum:

Predictors of improvement in patients with ankylosing spondylitis receiving anti-TNF

1. Background of the addendum

Anti-TNF are indicated in patients with ankylosing spondylitis (AS) who do not have a sufficient response to conventional therapeutic measures, including NSAIDs, and have been proven highly efficacious in reducing symptoms and inflammation.[1, 2]

Predictors of response to therapy may enable improved patient selection, outcomes and resource utilisation. The recommendations for anti-TNF use in AS are, however, based primarily on inadequate response to conventional therapies and less on the expectation that an anti-TNF agent will be effective in a particular patient.[1, 2] The literature continues to establish predictors of response, which are also associated with anti-TNF use in AS. Ideally, these may help clinicians to make evidence-based decisions that maximise the benefits from treatment by targeting subsets of patients most likely to respond; however, single predictors are too weak to be useful for decision-making in the individual patient.[3-10] Anti-TNF treatment is expensive and has potentially serious side effects. Predicting a good response might aid decision-making and improve the benefit/risk ratio in patients selected to start anti-TNF.

2. Aims

To determine predictors of improvement after 3 and 6 months months of treatment with anti-TNF in anti-TNF-naive patients. Importantly we aim at analysing prediction of improvement according to the recently developed ASDAS, for which scarce data is available.[11-13]

These aims are in line with the initially submitted research proposal.
3. Methods

Data extracted from BioReportEA will be analysed.

Variables will first be selected for univariate logistic regression analyses with 3-month and 6-month response criteria (in particular, ASDAS major improvement and ASDAS clinically important improvement) as the dependent variable.

Age, sex, disease duration, baseline CRP, HLA B27 status, smoking (ever/never), educational level, presence of swollen joints/enthesitis, ASDAS, BASDAI, BASFI and patient global assessments will be considered in univariate analysis.

Relevant variables will then be included in subsequent multivariate logistic regression analysis models, and non-significant variables will be removed from the model one at the time (starting with the least significant variable), checking for confounding, in order to achieve optimal model-fit.

4. Research team

- Proponents: Sofia Ramiro, Pedro Machado, Dra Maria José Santos
- Institutions involved: participation is open to all Portuguese centers interested in collaborating in this project. Co-authorship will be granted to a maximum of 4 co-authors per center, actively collaborating in the project
- External consultants: Prof. Robert Landewé, Prof. Désirée van der Heijde, Dr. Astrid van Tubergen (The Netherlands)

4. References


