

## **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. Inportantly 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

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