INTRODUCTION
Treatment options for multiple sclerosis (MS) have exponentially increased in the past decade. However, higher treatment efficacy brings treatment-related risks due to reduced immune competence. Hence, an unmet need for safer and more selective treatments targeted towards the cause of the disease remains. In this respect, antigen-specific tolerization with autologous tolerogenic dendritic cells (tolDC) is a promising approach.

OBJECTIVES
We assess the safety and feasibility of the therapeutic use of autologous tolDC in a well-defined population of MS patients in two single-center clinical trials, comparing intraderal (i.d., MS-tolDC, NCT02618902, Antwerp, BE) and intranal (i.n., TOLERVIT-MS, NCT02903537, Badalona, SP) administration.

MANUFACTURING PROCESS

STUDY OUTLINE

STUDY RESULTS: FIRST DOSE COHORT

PATIENT CHARACTERISTICS

ADVERSE EVENTS

MR1 RESULTS: NEW T2 AND GD+ LESIONS

CONCLUSION

According to a best-of-five design, patients are treated with ascending doses of tolDC in 3 cohorts, with interim analysis of safety by an independent Data Safety Monitoring Board (DSMB). Here, interim results of the first-dose cohort, treated with 5 × 10⁶ cells, are presented.

The on-study disease activity was not different as compared to pre-study activity according to the investigators.

Currently, the safety follow-up phase of the first dose cohort (n=6) is ongoing. While we consider the disease activity to be not significantly different from the pre-study phase, further follow-up is needed to demonstrate whether the observed MRI disease activity is treatment related or not.

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