The NDisc trial is an ongoing multicenter, randomized study with a sequential phase I study within the combined phase I/II trial with close monitoring of tolerability and safety. Twenty-four adult patients were randomized and treated with the investigational medicinal product NDisc plus or the carrier material only. Rates of adverse events in Phase I of this trial were comparable with those expected in the early time course after elective disk surgery. There was one reherniation 7 months after transplantation, which corresponds to an expected reherniation rate. Immunological markers like CRP and IL-6 were not significantly elevated and there were no imaging abnormalities. No indications of harmful material extrusion or immunological consequences due to the investigational medicinal product NDplus were observed. Therefore, the study appears to be safe and feasible. Safety analyses of Phase I of this trial indicate a relatively low risk considering the benefits that patients with debilitating degenerative disk disease may gain [1)].

1)
Tschugg A, Diepers M, Simone S, Michnacs F, Quirbach S, Strowitzki M, Meisel HJ, Thomé C. A prospective randomized multicenter phase I/II clinical trial to evaluate safety and efficacy of NOVOCART disk plus autologous disk chondrocyte transplantation in the treatment of nucleotomized and degenerative lumbar disks to avoid secondary disease: safety results of Phase I-a short report. Neurosurg Rev. 2017 Jan;40(1):155-162. doi: 10.1007/s10143-016-0781-0. Erratum in: Neurosurg Rev. 2017 Jan;40(1):177. PubMed PMID: 27567635.