

Results of a phase-I/II randomized, masked, placebo-controlled trial of recombinant human interleukin-11 (rhIL-11) in the treatment of subjects with active rheumatoid arthritis

ABSTRACT

During a 12-week trial, rhIL-11 was found to be safe and well-tolerated at various dosages and timings in patients with actively active RA. The only adverse event linked to the administration of the drug was an apparent reaction at the injection site.

INTRODUCTION

Introduction This study was designed to evaluate the efficacy and safety of recombinant human interleukin-11 (rhIL-11) in the treatment of active rheumatoid arthritis (AR) in a double-blind, placebo controlled trial (DCT). Participants were recruited via advertisement in the local newspaper and through a web-based recruitment service. Those who were interested in participating in the study were invited to complete an online questionnaire.

Methods:

The DCT was a randomized, double-blind, placebo controlled, controlled trial of recombinant human interleukin-11 (rhIL-11) in the treatment of active rheumatoid arthritis (The disease of RA is a chronic inflammation that affects around 1% of the population worldwide. There is no single regimen or combination of therapies that has consistently resulted in sustained improvement, and some disease-modifying drugs (e.g. methotrexate) are limited by significant toxicity that necessitates adjunct therapy or variable efficacy. Etanercept (sTNFR:Fc) and infliximab (chimeric anti-TNF monoclonal antibody) have been approved by regulatory agencies to treatment patients who had been treated with other patients with multiple A Phase-I/II masked, placebo-controlled trial was conducted on patients with active Crohn's disease to evaluate the safety of rhIL-11. The data demonstrated clinical benefit from the mean change in the CrADDS after 21 days at doses of 16 and 40 g/kg per week (P 0.05). The researchers concluded that a therapeutic effect of this adjuvant was effective at the time and that the results were encouraging. This led to the study'

CONCLUSION

Based on preliminary data, it is safe to administer rhIL-11 to patients with active RA at different doses and schedules safely, and no dose-limiting adverse event was observed. The dose setting of 15 g/kg once per week suggested a minimal therapeutic effect, an improvement in tender-joint counts. Further studies are needed to determine if higher or more frequent dose (i.e., placebo) is effective in treating autoimmune diseases.