Abstract / Povzetek predavanja

Efficacy and consumption of golimumab is similar with European and American dosing regimens in Ulcerative Colitis: Results of a prospective study

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BACKGROUND

Golimumab maintenance dosing for patients ≤80 kg differs between Europe and the United States [1–4].

AIM

Our aim was to compare efficacy, safety and drug consumption of both regimens in patients ≤80 kg.

MATERIAL AND METHODS

In this investigator initiated prospective study (ClinicalTrials.gov ID: NCT04156984) we recruited 29 consecutive patients with active ulcerative colitis. After a common induction, the first 15 patients received American regimen (100 mg every 4 weeks) and next 14 received European (50 mg every 4 weeks). In case of inadequate or loss of response (rectal bleeding score >0 or endoscopic Mayo ≥2), the dose was escalated to 100 mg in European group. Co-primary endpoints were endoscopic improvement (endoscopic Mayo score ≤ 1) at weeks 14 and 50 and clinical remission (rectal bleeding score = 0 and stool frequency score < 2) at weeks 14, 26, 38, and 50. Statistical analysis included Chi-square and Mann-Whitney tests.

RESULTS

Patient demographics are shown in Table 1. Endoscopic improvement, clinical remission rates, drug persistence and drug consumption are shown in (Figure 1). 8/14 (57%) of patients in European regimen needed dose escalation to 100 mg after a median of 8.6 weeks (interquartile range 6 to 14 weeks). In the American regimen 3 potentially drug-related side effects occurred.

CONCLUSIONS

In this prospective study, European and American golimumab maintenance regimens resulted in similar endoscopic improvement and clinical remission rates. Dose consumption was similar in both maintenance regimens.

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