

DTB CME/CPD Answers



▼ Daclizumab for MS

Question 1

Approximately how many people in the UK are estimated to have multiple sclerosis (MS)?

- a. 2,500
- b. 10,000
- c. 50,000
- d. 100,000**
- e. 250,000

Answer: d. MS is the most common demyelinating disease in the UK with a prevalence of about 0.16% (approximately 100,000 people) and an incidence of about 2,500 new cases every year.

Question 3

The SELECT trial evaluated the effect of subcutaneous daclizumab compared with placebo. What was the difference between daclizumab 150mg and placebo in terms of relapses per patient-year after 1 year of treatment?

- a. 0.07
- b. 0.17
- c. 0.25**
- d. 0.46
- e. 0.95

Answer: c. The difference between daclizumab 150mg and placebo was 0.25 relapses per patient-year (0.21 vs. 0.46; rate ratio [RR] 0.46, 95% CI 0.32 to 0.67; p<0.0001).

Question 2

The European Medicines Agency's review of clinical efficacy included one published phase II clinical trial and one published phase III clinical trial. Which one of the following statements regarding these studies is correct?

- a. Patients enrolled in the studies had a documented diagnosis of relapsing remitting MS with evidence of disease activity during the 6 months before randomisation
- b. The primary outcome was the proportion of patients with confirmed disability progression over the trial period
- c. Two-thirds of participants were men
- d. Patients who had previously received disease-modifying drugs were excluded from the studies
- e. A baseline Expanded Disability Status Scale (EDSS) score of ≤5 was part of the inclusion criteria in both studies**

Answer: e. In both trials, participants had to have evidence of disease activity during the 12 months before randomisation and a baseline EDSS score of ≤5.0.

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Question 4

Which one of the following was the most commonly reported adverse effect of daclizumab in the trials and their extensions?

- a. Infections
- b. Skin reactions
- c. Hepatic injury
- d. Malignancy
- e. Lymphadenopathy

Answer: a. Infections were the most commonly occurring adverse effects (58%; 4% serious).

Question 5

What proportion of daclizumab-treated patients experienced a skin reaction?

- a. 3%
- b. 9%
- c. 17%
- d. 32%
- e. 49%

Answer: d. Approximately 32% of daclizumab-treated patients had cutaneous reactions (2% serious) that included rash, eczema and allergic dermatitis and erythema.