

Domanda 1

Attività regolatorie per la conduzione di una sperimentazione clinica

Primary central nervous system (CNS) vasculitis, also known as primary angiitis of the CNS, is a rare form of vasculitis that is limited to the brain and spinal cord and causes a variety of neurologic syndromes.^{1,2} Because of its rarity and the similarity of some of these syndromes to more common disorders, primary CNS vasculitis is often misidentified. Descriptions of this condition date back only to the mid-1950s.³ Primary CNS vasculitis may occur in children, although this is uncommon. In this review, we focus on the disorder in adults



Domanda 2

Farmaco vigilanza: obiettivi fondamentali e gestione durante la conduzione dei trials clinici

Primary CNS vasculitis has had an estimated annual incidence of 2.4 cases per 1 million person-years in Olmsted County, Minnesota. The disorder affects persons of all ages, and its prevalence is similar among male and female patients.¹ Mortality has been reported to range from 8 to 23%, with approximately a quarter of patients having severe disability despite treatment.⁴⁻⁸ Factors associated with higher mortality include advanced age, cognitive impairment at the initial presentation, and cerebral infarctions on imaging.⁶ An estimated 40% of patients have unfavorable outcomes, and 5% do not survive long enough to be discharged from the hospital



Domanda 3

Creazione e gestione di una CRF (case report form) in un trial clinico

Clinical manifestations at the time of diagnosis vary and may suggest other, more common neurologic disorders. Table 1 summarizes the clinical manifestations observed in two clinical series.^{1,10} The most common manifestation at the initial presentation has been a sudden onset of focal neurologic deficits, which is suggestive of an ischemic event such as a stroke or transient ischemic attack that includes aphasia, ataxia, and visual-field defects. Other common features are headaches, progressive cognitive decline, and acute or subacute encephalopathy, which is often characterized by an acute confusional state that may progress to drowsiness and coma.

