Catalogo Articoli (Spogli Riviste)

OPAC HELP

Titolo:

EARLY TREATMENT OF STROKE WITH MONOSIALOGANGLIOSIDE GM-1 - EFFICACY AND SAFETY RESULTS OF THE EARLY STROKE TRIAL

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Titolo Testata:

Stroke

fascicolo: 8, volume: 25, anno: 1994,

pagine: 1552 - 1558

SICI:

0039-2499(1994)25:8<1552:ETOSWM>2.0.ZU;2-N

Fonte:

ISI

Lingua:

ENG

Soggetto:

CANADIAN NEUROLOGICAL SCALE; GM1 GANGLIOSIDE THERAPY; GUILLAIN-BARRE-SYNDROME; ACUTE ISCHEMIC STROKE; CEREBRAL-ISCHEMIA;

Keywords:

CLINICAL TRIALS; GANGLIOSIDES; STROKE MANAGEMENT;

Tipo documento:
Article
Natura:
Periodico
Settore Disciplinare:
Science Citation Index Expanded
Science Citation Index Expanded
Citazioni:
21
Recensione:
Indirizzi per estratti:
Citazione:
G.L. Lenzi *et al.*, "EARLY TREATMENT OF STROKE WITH MONOSIALOGANGLIOSIDE GM-1 - EFFICACY AND SAFETY RESULTS OF THE EARLY STROKE TRIAL", *Stroke*, 25(8), 1994, pp. 1552-1558

Abstract

Background and Purpose The Early Stroke Trial (EST) is a randomized, double-blind, placebo-controlled trial to assess the effect of monosialoganglioside GM-1 in improving recovery in patients who experienced an ischemic supratentorial stroke. Methods Sixteen clinical centers recruited 805 patients, of whom 792 were confirmed to be eligible. Treatment, consisting of a first dose of either 200 mg GM-1 or placebo, was initiated within 5 hours of the onset of stroke; a second dose of either 100 mg GM-1 or placebo was administered 12 hours later. Thereafter,patients received a daily injection of 100 mg GM-1 or placebo intravenously from day 2 through 10 and intramuscularly from day 11 through 21. Patients were followed up for a total of 4 months. Results Survivalwas similar in the two treatment groups. Improvement in neurological status, as measured by the change in Canadian Neurological Scale scorebetween baseline and 4-month assessments, was greater in the group receiving GM-1; the observed difference between treatment groups was 0.22 (P=.06). A post hoc analysis in the subgroup of patients treated within 4 hours showed a statistically significant difference, with Canadian Neurological Scale mean improvement of 0.41 (P=.016). GM-1 use was not associated with differences in frequency, nature, or severity of adverse experiences. Conclusions These findings suggest that GM-1 is safe in the dose and treatment schedule used and that its efficacy in ischemic stroke is greater when given soon after onset of stroke.
