ANAGRELIDE: ANAHYDRET study

Anagrelide compared with hydroxyurea in WHO-classified essential thrombocythemia: the ANAHYDRET Study, a randomized controlled trial.

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Abstract

High platelet counts in essential thrombocythemia (ET) can be effectively lowered by treatment with either anagrelide or hydroxyurea. In 259 previously untreated, high-risk patients with ET, diagnosed according to the World Health Organization classification system, the efficacy and tolerability of anagrelide compared with hydroxyurea were investigated in a prospective randomized noninferiority phase 3 study in an a priori-ordered hypothesis. Confirmatory proof of the noninferiority of anagrelide was achieved after 6 months using the primary end point criteria and was further confirmed after an observation time of 12 and 36 months for platelet counts, hemoglobin levels, leukocyte counts ($P < .001$), and ET-related events (HR, 1.19 [95% CI, 0.61-2.30], 1.03 [95% CI, 0.57-1.81], and 0.92 [95% CI, 0.57-1.46], respectively). During the total observation time of 730 patient-years, there was no significant difference between the anagrelide and hydroxyurea group regarding incidences of major arterial (7 vs 8) and venous (2 vs 6) thrombosis, severe bleeding events (5 vs 2), minor arterial (24 vs 20) and venous (3 vs 3) thrombosis and minor bleeding events (18 vs 15), or rates of discontinuation (adverse events 12 vs 15 or lack of response 5 vs 2). Disease transformation into myelofibrosis or secondary leukemia was not reported. Anagrelide as a selective platelet-lowering agent is not inferior compared with hydroxyurea in the prevention of thrombotic complications in patients with ET diagnosed according to the World Health Organization system.
This trial was registered at http://www.clinicaltrials.gov as #NCT01065038.