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Comparison of operational criteria for treatment outcome in gambiense human African trypanosomiasis

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Sleeping sickness or human African trypanosomiasis in West and Central Africa is caused by Trypanosoma brucei gambiense. The infection progresses from a haemo-lymphatic or first stage to a meningo-encephalitic or second stage, once parasites reach the central nervous system. After treatment, trypanosomiasis patients should be followed for 2 years before they can be considered cured. Relapse after treatment is unambiguously diagnosed by the presence of trypanosomes in blood, lymph and/or cerebrospinal fluid. If trypanosomes are not detected, diagnosis of relapse is based on the absolute number of, and/ or increase in white blood cells in cerebrospinal fluid with or without neurological symptoms. Currently, white blood cell count based criteria to define relapse or cure are not standardized. As a consequence, the impact of the different criteria for relapse on the outcome and comparability of clinical trials remains unknown.

The specificity, sensitivity and time to diagnosis of 10 criteria for relapse based on trypanosome detection and/or the white blood cell count in cerebrospinal fluid were compared in 63 relapsed and 247 cured *Trypanosoma brucei gambiense* patients. Among the criteria in use, the "presence of trypanosomes or a cerebrospinal white blood cell count $\geq 50/\mu$ l" can be recommended as the criterion to identify relapses after treatment for *Trypanosoma brucei gambiense* human African trypanosomiasis, irrespective of disease stage.