

Campath treatment suspended after serious risks found

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Treatment with the immune-suppressing monoclonal antibody Campath (alemtuzumab) in a comparative clinical trial with the beta interferon Rebif has been suspended. The phase 2 trial in relapsing remitting MS involves 334 people at 49 centres in Europe and the U.S.

Reporting first-year results of the three-year trial, Genzyme Corporation and Schering AG said that, while Campath was very effective in reducing MS attacks, serious adverse effects had occurred.

Patients on the trial were being treated once a year with low or higher dose infusions of Campath or the standard dose of Rebif administered three times per week. The companies have suspended giving the drug to participants but say that they will continue to collect data on efficacy and safety as they begin planning for a more definitive phase 3 trial.

Three people on Campath developed severe idiopathic thrombocytopenic purpura (ITP), a condition in which low blood platelet counts can lead to abnormal bleeding. One of these patients died, as did another from unknown causes. ITP is a condition normally curable with well-tolerated treatments. Other adverse effects included two patients who developed Graves disease, an autoimmune thyroid condition identified as a risk in previous studies of Campath in MS, and one case of listeria meningitis.

The companies have notified participants and regulatory authorities about the risk of ITP. They are working to develop tests which would provide earlier indications of possible adverse side effects or help identify patients who might be more at risk for adverse events. They said that Campath should not be used 'off-label' at the moment for the treatment of MS.
