

Previously unpublished trial data explain effects and side effects of key MS drug

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Alemtuzumab is a highly effective drug for multiple sclerosis, approved in more than 60 countries and used by more than 12,000 patients worldwide. However, there is an almost 50 per cent risk of secondary autoimmune diseases, some of which are life-threatening, such as platelet and kidney diseases.

Although knowledge about these adverse effects was included in conference presentations and licensing submissions to European and US regulators, critical data to explain secondary autoimmune disease had not been scrutinised and published following peer review.

Through a Freedom of Information request to the European Medicines Agency (EMA) researchers from Queen Mary University of London (QMUL) gained access to the phase III trial datasets of Alemtuzumab.

Their analysis and interpretation, results of which are published in *JAMA Neurology*, provides new insights into the drastic responses of the immune system in people with MS taking Alemtuzumab.

The researchers discovered a massive and rapid re-population of a subset of B cells in the absence of effective T cell regulation, which they say helps create an environment for secondary autoimmune disease. This also allows a marked anti-drug response that can become problematic in some people taking the drug.

According to the researchers, controlling this B cell subset "overshoot"

after Alemtuzumab administration until T cell regulation recovers, may limit the risk of secondary autoimmune disease and make it an even better medicine.

Additionally, whilst they saw a long term suppression of T cells believed by many to be the cause of the problem. They also saw loss of memory B [cells](#), which they say offers a new explanation on why Alemtuzumab is effective in people with MS. Indeed it may provide insight of how all other drugs work in MS and ties aspects of the potential cause and treatments together.

Lead author Dr Klaus Schmierer from QMUL said: "We were very surprised to find such important information on B cell dynamics were only partially described and remained unpublished, even though they were observed and analysed several years ago following the pivotal phase III trials.

"Interrogating the original data from a different perspective opened our minds to alternative explanations. This made us discard the science dogma that we think is leading people to look in the wrong place for solutions.

"This new information will help contribute to the effective management of people with MS, firstly during the decision process about disease modifying treatment, and secondly in people who have been treated with Alemtuzumab, to ensure the risks associated with dangerous side effects are minimised.

"There remain some unanswered questions, based on what we saw. This shows us why it is important for total transparency and total access to all anonymous trial data.

"Whilst we appreciate release of data is part of the drug-marketing

process, it is in the public interest that all information collected is made unconditionally available, within a reasonable time frame."

More information: *JAMA Neurology* (2017). [DOI: 10.1001/jamaneurol.2017.0676](https://doi.org/10.1001/jamaneurol.2017.0676)

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