# A multicentre randomiSed controlled TRial of IntraVEnous immunoglobulin compared with standard therapy for the treatment of transverse myelitis in adults and children (STRIVE)

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# Plain English summary

## The STRIVE study

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# Plain English summary

Transverse myelitis (TM) is a rare immune disorder that affects the spinal cord. Patients who develop TM can quickly lose the feeling in and the ability to move lower parts of the body (paraplegia). Additionally, the upper body can also be affected (tetraplegia). TM can affect people at any age and can have a significant impact on quality of life and place a large demand on health resources.

Although immune treatments such as steroids, intravenous immunoglobulin (IVIG) and plasma exchange are being used to treat TM, until now, no high-quality trial has been conducted to measure how effective these treatments are when utilised individually or in combination. Therefore, this randomised controlled trial was designed to see whether or not newly diagnosed TM patients would benefit from early treatment with IVIG if added to steroid therapy, which we expect all patients to receive. We measured the effect of treatment using the American Spinal Injury Association (ASIA) Impairment Scale, an outcome measure that has been validated in spinal injury research, and using evaluators who were not aware of the treatment that patients had received (single blind).

After 1 year, despite 15 centres recruiting across the UK, only two patients were randomised. The key reasons for this include the strict inclusion criteria, the short enrolment window, the challenges associated with the use of the ASIA Impairment Scale as the primary outcome measure, an inaccurate estimation of the incidence of TM and the spectrum of severity within the target population and inadequate funding provision for some sites. As 170 cases were required to determine a statistically significant effect of treatment, the study was closed early as this end point would not have been realistically achieved. However, we are now aware of important factors that need to be addressed when undertaking a trial in TM or an allied rare condition.

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