



Efficacy and safety of MRI-based thrombolysis in wake-up stroke: a randomised, double-blind, placebo-controlled trial

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15.9 M€

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Budget
1 145 870 €



Source : <https://www.wakeup-stroke.eu>

Currently, acute stroke treatment depends on knowing when the symptoms began. The European consortium Wake-Up worked on a method to determine the time window for therapy.

WAKE-UP is an investigator-initiated, multicentre, randomised, double-blind, placebo-controlled trial designed to test efficacy and safety of MRI-based intravenous thrombolysis in patients with wake-up stroke. Every year 1.5 million patients suffer a stroke in the EU. Up to 20% of stroke patients wake up with stroke symptoms. Currently these patients are not eligible for thrombectomy whereas it is the only approved reperfusion therapy available for acute ischemic stroke. However, recently the potential of MRI to identify patients likely to be within a time-window for thrombolysis (≤ 4.5 hours) was demonstrated. WAKE-UP used a specific MRI pattern, i.e. the mismatch between a visible lesion on diffusion weighted imaging (DWI) and a normal fluid attenuated inversion recovery (FLAIR) image, to randomise patients waking up with stroke symptoms to either treatment with Alteplase or placebo. A total of 503 patients were enrolled in 40 centres in six EU countries and it resulted in a significantly better functional outcome and numerically more intracranial hemorrhages than placebo at 90 days. Software were developed to facilitate the processing and analysis of multiparametric stroke MRI and to assist the integration of modern stroke imaging into acute treatment decisions. The trial has been accompanied by activities increasing the awareness for acute stroke in the public and results were disseminated within the scientific community as well as within the public with a publication in the *New England Journal of Medicine*. WAKE-UP aimed to promote a paradigm-change in acute stroke treatment, and to provide effective treatment to a large new group of patients. The results of WAKE-UP expect to change guidelines of acute stroke management and clinical practice. WAKE-UP will help to reduce the burden of stroke related disability in the EU.

More information on: <https://www.wakeup-stroke.eu>

