



WAKE UP Clinical Trial Update

November 2017



About The WAKE-UP



- WAKE-UP is a European multicentre investigator-initiated randomized placebo-controlled clinical trial of MRI based thrombolysis in acute stroke patients with unknown time of symptom onset, e.g. due to recognition of stroke symptoms on awakening.
- The objective of WAKE-UP is to test efficacy and safety of MRI-based intravenous thrombolysis with Alteplase in patients waking up with stroke symptoms or patients with unknown symptom onset. By this, WAKE-UP aims at providing a new safe and effective treatment option for acute stroke patients waking up with stroke symptoms.
- The Project started in 2013.
- As of June 30, enrolment in the WAKE-UP trial was stopped following a decision by the Steering Committee. By the end of enrolment, 1,377 patients were enrolled in WAKE-UP with 501 patients randomized and 876 screen failures.



The WAKE-UP Project Update

- WAKE-UP is a European collaborative research project launched by a consortium of academic and SME partners destined to improve the treatment of stroke patients.
- The core of WAKE-UP is an investigator-initiated randomized controlled trial of MRI based thrombolysis in patients waking up with stroke symptoms.
- WAKE UP was led by an active and motivated consortium combining central trial management with decentralised organisation with national coordinators, with a clear communication structure and share of responsibilities, which led to the successful completion of the project.



The WAKE-UP Project Update

- During the WAKE UP trial, imaging software (SONIA) was developed for the purpose of this project, yet this software can also be used even when WAKE UP trial is done, for other research projects in the future.
- One of the collateral benefits of this project was that clinicians/ investigators were trained in reading MRI images, providing a learning opportunity for these stroke professionals in the interpretation of MRI in acute stroke diagnostics. Almost 400 investigators from eight European countries participated in a structured software-based training.



The WAKE-UP Project Update

- WAKE UP trial proved to be a good example on how to involve patients who are unable to give consent.
- Repeated interim analysis of safety data from the trial and evaluation by the independent Data and Safety Monitoring Board already showed that the intervention performed in this trial was proven to be safe for patients.
- The final results of the main research will be presented to the public in May 2018 at ESOC 2018 conference.



The final note

WAKE-UP - The work leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 278276.

