MISTIE

This study, was designed to confirm these preliminary findings in a larger number of patients. The hope is that the MISTIE approach can improve patient's long-term quality of life. The primary endpoint is a outcomes assessment called the Modified Rankin Scale measured at 180 and 365 days after the stroke.

MISTIE III Clinical Trial

MISTIE III (Minimally Invasive Surgery Plus rtPA for intracerebral hemorrhage surgery evacuation) is an international, Phase III, 500-patient clinical trial with the primary goal of defining a successful intracerebral hemorrhage treatment.

MISTIE III is funded by the National Institute of Neurological Disorders and Stroke (NINDS), one of the National Institutes of Health (NIH), under a cooperative agreement (U01).

It involve over 90 centers in the US, Europe, Israel, China and Australia. The trial is led by Study Chairman and Co-Principal Investigator Dr. Daniel Hanley of Johns Hopkins University and coordinated by the Brain Injury Outcomes service (BIOS) in the Department of Neurology. There are two surgical coordinating centers: University of Chicago, led by Co-Principal Investigator Dr. Issam Awad and the University of Cincinnati lead by Co-Principal Investigator Dr. Mario Zuccarello.

ClinicalTrials.gov Identifier: NCT01827046

International Standard Randomised Controlled Trial Number Register (ISRCTN) Identifier: ISRCTN81927110

NIH/NINDS Cooperative Agreement: 1U01NS080824-01A1

The MISTIE III intervention seeks to remove blood from the brain through minimally invasive surgery and intermittent dosing of a clot-busting drug, a recombinant tissue plasminogen activator (rt-PA) called alteplase, sold under the tradenames of Cathflo Activase by Genentech in the US and as Actilyse by Boehringer Ingelheim in Europe and Asia. The study premise is that by removing the blood clot faster, injury to the brain will be reduced and the patient’s long-term prognosis will improve.

MISTIE II Clinical Trial

MISTIE II, was completed in April 2013. That study suggested that this investigational treatment may offer a possible new treatment for this devastating condition.

Hanley et al., assessed whether minimally invasive catheter evacuation followed by thrombolysis (MISTIE), with the aim of decreasing clot size to 15 mL or less, would improve functional outcome in patients with intracerebral haemorrhage.

For moderate to large intracerebral haemorrhage, MISTIE did not improve the proportion of patients who achieved a good response 365 days after intracerebral haemorrhage. The procedure was safely adopted by a sample of surgeons 1)
They used a computer-generated allocation sequence with a block size of four to centrally randomise patients aged 18-80 years with a non-traumatic (spontaneous) intracerebral haemorrhage of 20 mL or higher to standard medical care or image-guided MIS plus alteplase (0.3 mg or 1.0 mg every 8 h for up to nine doses) to remove clots using surgical aspiration followed by alteplase clot irrigation. Primary outcomes were all safety outcomes: 30 day mortality, 7 day procedure-related mortality, 72 h symptomatic bleeding, and 30 day brain infections. This trial is registered with ClinicalTrials.gov, number NCT00224770.

Between Feb 2, 2006, and April 8, 2013, 96 patients were randomly allocated and completed follow-up: 54 (56%) in the MIS plus alteplase group and 42 (44%) in the standard medical care group. The primary outcomes did not differ between the standard medical care and MIS plus alteplase groups: 30 day mortality (four [9·5%, 95% CI 2·7-22.6] vs eight [14·8%, 6·6-27·1], p=0·542), 7 day mortality (zero [0%, 0-8·4] vs one [1·9%, 0-1-9·9], p=0·562), symptomatic bleeding (one [2·4%, 0-1-12·6] vs five [9·3%, 3-1-20·3], p=0·226), and brain bacterial infections (one [2·4%, 0-1-12·6] vs zero [0%, 0-6·6], p=0·438). Asymptomatic haemorrhages were more common in the MIS plus alteplase group than in the standard medical care group (12 [22·2%; 95% CI 12·0-35·6] vs three [7·1%; 1-5-19·5]; p=0·051).

MIS plus alteplase seems to be safe in patients with intracerebral haemorrhage, but increased asymptomatic bleeding is a major cautionary finding. These results, if replicable, could lead to the addition of surgical management as a therapeutic strategy for intracerebral haemorrhage ²).

In December of 2016, phase 2 of the Minimally Invasive Surgery Plus Rt-PA for ICH Evacuation (MISTIE) study demonstrated that this form of stereotactic thrombolysis safely reduces clot burden and may improve functional outcome 6 months after injury. A smaller arm of this study, the Intraoperative Stereotactic Computer Tomography-Guided Endoscopic Surgery (ICES) study, also demonstrated feasibility and good functional outcome for endoscopic minimally invasive evacuation. Early-phase clinical studies evaluating various forms of minimally invasive surgery for intracerebral hemorrhage evacuation have shown safety and feasibility with a preliminary signal towards improved functional long-term outcome. Results from phase 3 studies addressing various minimally invasive techniques are imminent and will shape how intracerebral hemorrhage is treated ³).

MISTIE was an open-label, phase 2 trial that was done in 26 hospitals in the USA, Canada, the UK, and Germany.

Hanley et al. used a computer-generated allocation sequence with a block size of four to centrally randomise patients aged 18-80 years with a non-traumatic (spontaneous) intracerebral haemorrhage of 20 mL or higher to standard medical care or image-guided minimally invasive surgery (MIS) plus alteplase (0.3 mg or 1.0 mg every 8 h for up to nine doses) to remove clots using surgical aspiration followed by alteplase clot irrigation. Primary outcomes were all safety outcomes: 30 day mortality, 7 day procedure-related mortality, 72 h symptomatic bleeding, and 30 day brain infections. This trial is registered with ClinicalTrials.gov, number NCT00224770.

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MIS plus alteplase seems to be safe in patients with intracerebral haemorrhage, but increased asymptomatic bleeding is a major cautionary finding. These results, if replicable, could lead to the addition of surgical management as a therapeutic strategy for intracerebral haemorrhage 4).

References


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