

Moleac wins Singapore Entrepreneurial Company of the Year Award

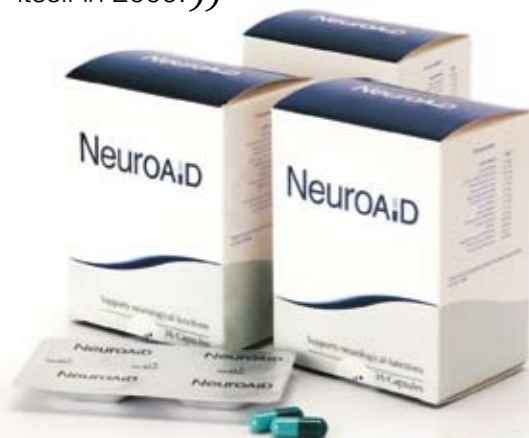


“Moleac has identified a need gap in the stroke recovery process and has adopted an innovative approach to address this void. NeuroAiD™, the company's flagship product is derived from Traditional Chinese Medicine (TCM) and helps patients recover functional skills in the post stroke rehabilitation process - addressing a gap that has not been filled by western medicine.

The approach of taking from TCM to fill a gap in western treatment options is not only innovative but is also highly efficient in terms of product commercialization. As the efficacy of TCM is proven, the company has been able to develop the NeuroAiD™ with relatively low investments and commercialize it in a relatively short period span of less than 5 years.

In the short period since its launch, NeuroAiD™ has become a product with global reach. It has witnessed considerable geographic expansion outside its home country, Singapore and is available not only in multiple countries in the Asia Pacific region, but also in the Middle East, Europe and US. The success of the product is evident in the dramatic revenue growth between 2006 and 2008 and the aggressive multi-million dollar targets that the company has set for itself in 2009.”

Sohini Mitra - Frost & Sullivan



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A novel approach for stroke recovery: NeuroAid

NeuroAid™
is a product of Moleac

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A novel approach for stroke recovery: NeuroAid

Cerebrovascular disease is the world's second leading cause of death and is projected to remain so for the foreseeable future. It is estimated that by 2030, cerebrovascular disease will be responsible for 10.6 percent of deaths and will be the sixth leading cause of disability-adjusted life years. [PLoS Med 2006 Nov;3(11):e442]

Acute care of stroke has improved but many patients are ineligible for such therapies, or do not present in time to receive them. There is also a lack of pharmacological modalities for longer-term stroke recovery; many molecules have shown early promise but none have made the grade in clinical trials. As a result, a large number of stroke patients make only a poor recovery and are left with chronic disabilities. There is an urgent need for widely-applicable new approaches to tackle this burden, in order to relieve the considerable strain placed on healthcare systems, patients and their families.

Improving functional outcomes in stroke: A novel approach

The choice of stroke treatments may be limited in the West but in China several traditional Chinese medicine (TCM) agents have been approved for clinical use by the Chinese National Drug Administration. However, clinical trials performed in China have traditionally been hampered by poor methodology and a lack of awareness and acceptance of TCM outside the country. This situation is now beginning to change and TCM is rapidly moving into the realm of Western-style clinical trials and evidence-based medicine.

One of the best-studied TCMs – Danqi Piantang Jiaonang (NeuroAid™, Moleac) – may hold promise for improving stroke outcomes, according to a recent study published in the journal *Stroke*. Chen *et al.* compiled data from two previously unpublished randomized clinical trials, comparing NeuroAid against another widely-used stroke TCM known as Buchang Naoxintong Jiaonang (BNJ). The trials involved a total of 605 subjects aged 18 to 70, who had a recent Western-standard diagnosis of ischemic stroke and a TCM-standard diagnosis of apoplexy. Patients took four capsules three times a day. [Stroke 2009 Mar;40(3):859-63]

Independence and motor function

After a month of treatment, NeuroAid

patients showed significant improvements in independence and functional outcomes compared to BNJ patients (Figure 1). Using the Comprehensive Function Score component of the Diagnostic Therapeutic Effects of Apoplexy (DTER) scale, NeuroAid patients were 2.4 times as likely to have a good functional outcome as those taking BNJ (relative risk 2.4; 95 percent CI 1.28 to 4.51; $P=0.007$).

NeuroAid also fared well in specific analyses of motor function (Figure 2). For upper limb function, NeuroAid patients scored a mean of 0.43 points lower on the DTER scale (95 percent CI, -0.73 to -0.12; $P=0.006$), and for distal lower limb function they scored a mean of 0.32 points lower (95 percent CI, -0.59 to -0.06; $P=0.02$). Non-significant decreases were also observed in domains of lower limb, distal upper limb and facial function. There was no significant difference between groups for language and visual function. A trend towards improved neurological deficit outcomes with NeuroAid was also noted, but did not reach significance.

Case reports: Full recovery in six out of 10 patients

NeuroAid is approved for use in 10 countries and is undergoing registration in a further six. It has already entered clinical usage in Singapore, and promising results have been published from a series of 10 patients (Table 1). They started NeuroAid therapy between 1 week and 6 months after presentation with ischemic stroke – taking four NeuroAid tablets three times a day, in combination with regular medications, as dictated by their condition. [Eur Neurol 2008;60(5):264-6]

All of the patients displayed improvement in at least one domain. Six out of 10 made a full recovery – one within 2 weeks, one within 2 months, three within 3 months and one within 7 months. Of the remaining patients, three made a good or moderate recovery and one made a poor recovery.

Motor improvements were observed in eight patients after initiation of NeuroAid treatment, including improvements in hemiplegia (for both patients with left-sided and with right-sided paralysis at presentation) and resolution of weakness or numbness of the upper and lower limbs (from a range of baseline severities). Speech and vision also improved in several patients following NeuroAid therapy: four showed improvement of speech difficulties such as anomia and apha-

Figure 1: Effect of NeuroAid on functional outcome at 1 month.

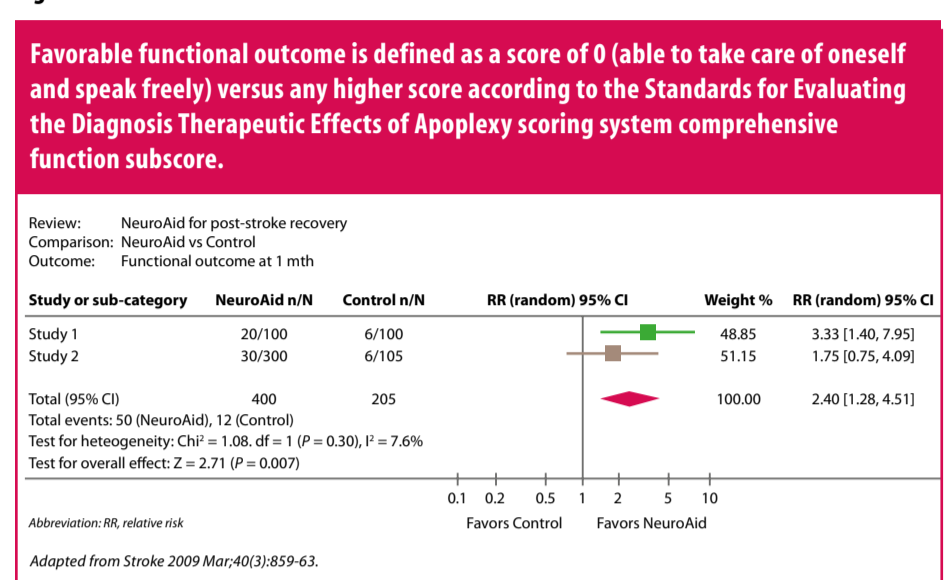
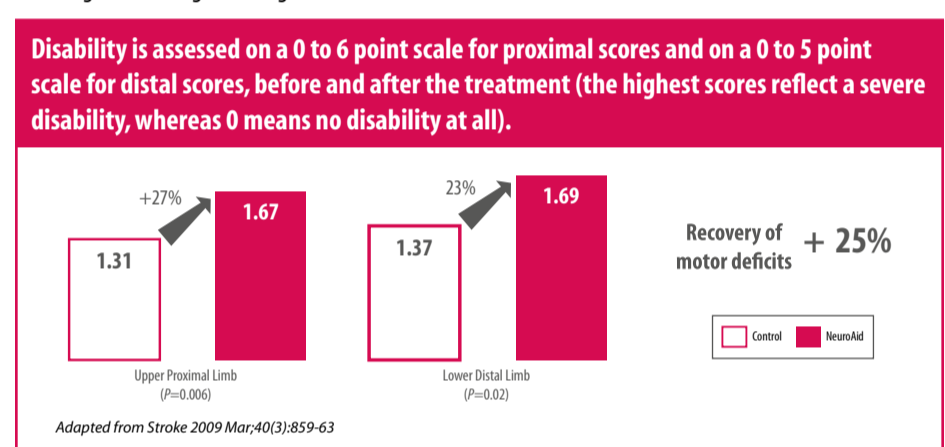


Figure 2: Recovery of motor function in stroke patients taking NeuroAid, as compared to those taking Buchang Naoxintong Jiaonang.



sia, while five reported resolution of visual hemianopia and diplopia. Balance problems also resolved in all three patients who had experienced difficulties after stroke.

The results are very promising, especially given that three patients started taking NeuroAid at a late stage in their recovery period. One particular patient did not start NeuroAid treatment until 6 months after his stroke, having reached a plateau in his recovery, and subsequently reported improvements in his speech and motor abilities.

NeuroAid: Safe and tolerable

Results from the study by Chen *et al.* also suggest that NeuroAid is safe and well tolerated. There were no serious adverse events in either of the clinical trials, and just two cases of vomiting and nausea in patients receiving NeuroAid. There were no abnormal changes in liver function, renal function or blood cell count.

Further support for the safety profile of NeuroAid comes from a series of three studies published last year, which found that the drug did not affect hemostatic parameters in healthy volunteers – either in combination with, or without, aspirin. [Cerebrovasc Dis 2008;25(5):450-6] The parameters tested included fibrinogen, activated partial thromboplastin time, prothrombin time, platelet aggregation and D-dimer.

The studies also showed that NeuroAid did not affect biochemical, hematological or hemostatic parameters in 10 ischemic stroke patients, who took the drug in combination with other concomitant standard medications. Measurements were taken at baseline, 1 and 4 weeks after NeuroAid initiation, and included fasting glucose, creatinine, C-reactive protein, alanine aminotransferase, aspartate transaminase and complete blood count. There were no adverse events in any of the three studies.

Looking ahead

The momentum for NeuroAid is gathering. It has culminated in the launch of a large-scale randomized controlled trial – the first-ever to apply international Good Clinical Practice guidelines in the assessment of a TCM for acute ischemic stroke. [Int J Stroke 2009 Feb;4(1):54-60] The Chinese Medicine Neuroaid Efficacy on Stroke Recovery (CHIMES) study will compare NeuroAid against placebo, with an intended cohort of 1,100 individuals. The study is presently recruiting in Singapore and the Philippines, and may expand its intake to include patients from Malaysia, Hong Kong, Indonesia, Thailand, Korea, Pakistan and Sri Lanka.

CHIMES will include patients who are on antiplatelet therapy and present within 48 hours of onset of ischemic stroke. The primary endpoint is grade on the modified Rankin Scale, assessed at 3 months. There are a range of secondary endpoints for efficacy, including scores on the National Institutes of Health Stroke Scale, Barthel Index and the Mini Mental State Examination. Safety outcomes will include liver and renal tests, electrocardiography and complete blood count.

The international neurology community is eagerly awaiting the publication of the CHIMES trial. The results will reveal whether NeuroAid therapy should be initiated systematically at the early stages of stroke, and how it can improve long-term functional outcomes in stroke patients. There are also a number of other case reports in press regarding the extension of the indications for NeuroAid. It is hoped that the coming years will shed new light on the role and function of NeuroAid, and establish whether incorporating this traditional Chinese remedy into routine clinical practice will alleviate the suffering of stroke patients across the globe. **MI**

Table 1: Recovery of stroke patients with NeuroAid in a recently published case series.

Patient number	Time since stroke	Assessment	Improvement areas			
			Motor	Balance	Vision	Speech
1	1 wk	Full Recovery (2 mths)	✓			✓
2	1 wk	Full recovery (7 mths)		✓		
3	2 wks	Full Recovery (3 mths)	✓		✓	
4	1 wk	Full Recovery (3 mths)	✓	✓	✓	
5	1 wk	Full Recovery (2 wks)	✓	✓	✓	
6	1 mth	Full Recovery (3 mths)			✓	
7	1 mth	Very Good Recovery: Only residual acalculia (1 mth)	✓		✓	✓
8	6 mths	Very Good Recovery: Only residual mild aphasia (3 mths)	✓			✓
9	1 wk	Moderate Recovery: Residual motor deficit: strength 4/5 RUE, 4-/5 RLE (2 mths)	✓			
10	1 wk	Poor Recovery: Strength 1/5 RUE, 2/5 RLE, 5/5 LUE-LLE, can turn over and make noises (3 mths)	✓			✓
Total			8	3	5	4

Abbreviations: LLE, left lower extremities; LUE, left upper extremities; RLE, right lower extremities; RUE, right upper extremities.

Adapted from Eur Neurol 2008;60(5):264-6.