

# A placebo-controlled trial shows no effect of a vasopressin analogue (DGAVP) on subjective and cognitive recovery immediately after mild head injury

## Citation for published version (APA):

Twijnstra, A., Bohnen, N., & Jolles, J. (1992). A placebo-controlled trial shows no effect of a vasopressin analogue (DGAVP) on subjective and cognitive recovery immediately after mild head injury. *Neurology*, 42(S3), 328. [639P].

## Document status and date:

Published: 01/01/1992

## Document Version:

Publisher's PDF, also known as Version of record

## Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
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injured segmental structures was done after a 72-hour recovery. Aspartate, GABA, glutamate, glycine, and taurine were measured before, during, and after prolonged transcranial motor cortex stimulation and quantified using HPLC.

**Results.** No changes in AANT levels occurred in either injury group from stimulation, compared to sham controls (n = 5). Severely

injured flaccid animals had glycine levels 2-3 times higher ( $p < 0.001$ ) than either mild/moderate, spastic animals or controls.

**Conclusions.** High concentration of the inhibitory AANT glycine is associated with flaccidity or SS but not spasticity. Glycinergic compounds directed toward suppression of excess muscle tone in spastic conditions deserve further study.

## **Amputation with Functional Electrical Stimulation (FES) in Individuals with Paraplegia and Incomplete Quadriplegia**

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Commercial application of computer-assisted functional electrical stimulation (FES) is being promoted as a rehabilitation technology for motor disability. Experience with such devices has been primarily limited to research laboratories or those institutions participating in their development.

The Parastep System is a commercially available, battery powered, microprocessor controlled, four- or six-channel stimulator which uses surface electrodes applied to skin to activate lower-extremity muscles for standing and taking steps. Programmed functions are initiated through switches located on the hand grips of a modified rolling walker. With training, users are able to assume and maintain a biped upright posture and activate reciprocal steps to achieve effective locomotion over level surfaces.

Between 1990 and 1992 the Parastep System was employed as an assistive device for walking in 41 individuals with paraplegia and

incomplete quadriplegia. Male to female ratio was 3:1. Sixty-one percent had complete thoracic cord injuries T12 or higher, 32% incomplete thoracic injuries and 7% incomplete cervical injuries below C6. Twenty-five remain in the investigational program. Eleven could not complete training for medical or personal reasons. To date, 12% have completed 32 physical therapy sessions over an average of 18.5 weeks and are independent ambulators. This group ambulates with the device over 200 feet without resting.

Preliminary observations indicate that (1) independent ambulation is possible in individuals with complete and incomplete paraplegia using a commercially available computer controlled FES system; (2) patient motivation, pre-injury activity habits and general health status appear to correlate with successful ambulation; and (3) obstacles to successful ambulation include patient compliance, articular changes and postural deformities.

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## **A Placebo-Controlled Trial Shows No Effect of a Vasopressin Analogue (DGAVP) on Subjective and Cognitive Recovery Immediately After Mild Head Injury**

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**Objective.** The aim of the study was to investigate whether the administration of a behaviorally active neuropeptide (DGAVP) has a beneficial effect on the subjective and cognitive recovery from mild head injury.

**Background.** The vasopressin (VP) derivative DGAVP has consistently failed to show a beneficial effect in patients with moderate to severe cognitive dysfunctions, but significant peptide effects have been found in various studies with healthy volunteers. There is a paucity of well-controlled studies of DGAVP in patients with only mild cognitive dysfunction.

**Design.** The study was performed according to a double-blind placebo-controlled matched pairs design (N = 36). The peptide was administered for 3 months (daily dose 2 mg intra-nasal) starting from the second day after mild head injury (MHI). There were 6 neuropsychological assessments.

**Results.** Repeated measures analysis of variance did not reveal a significant treatment effect for any of the cognitive parameters or subjective recovery.

**Conclusions.** The results of this study do not support the hypothesis that DGAVP may have a therapeutic effect in MHI patients.

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## **The Effect of Idebenone on Recovery from Stroke**

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**Objective.** Phase II trial of idebenone on recovery of neurologic function following ischemic stroke.

**Background.** Idebenone is currently marketed in Japan to enhance recovery from stroke. Idebenone is thought to function as a coenzyme Q analog, enhancing mitochondrial respiration and inhibiting lipid peroxidation in ischemic brain.

**Design/Methods.** This is a randomized, double-blind, placebo-controlled study of patients admitted for inpatient rehabilitation following ischemic stroke. Outcome variables were assessed at baseline and 9 weeks, or upon discharge or withdrawal from study. Scores were compared with a two-tailed *t* test.

**Results.** Fifty-seven patients were enrolled a mean of  $36 \pm 2$  (SEM) days post-stroke for a duration of  $40 \pm 4$  days. Treatment and placebo groups were similar at baseline. Final outcome variables for the idebenone vs. placebo groups respectively were as follows: Barthel Index  $68 \pm 4$  vs.  $69 \pm 4$ ; Fugl-Meyer motor score  $50 \pm 7$  vs.  $62 \pm 6$ ; Mini-Mental State  $23 \pm 2$  vs.  $25 \pm 1$ ; Western Aphasia Battery cortical quotient  $80 \pm 6$  vs.  $85 \pm 4$  and aphasia quotient  $83 \pm 7$  vs.  $87 \pm 5$ ; and Hamilton Depression Scale  $5 \pm 1$  vs.  $4 \pm 1$ .

**Conclusion.** We found no statistically significant benefit from the use of idebenone in the subacute phase post-stroke.

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