Bioxtreme

Plaxtreme Clinical Trial

Single-center feasibility study in inpatient hand rehabilitation

REUTH TLV Rehabilitation Hospital
Post-stroke and post-TBI participants

Randomized, open-label, two-arm design with Plaxtreme and standard rehabilitation vs. standard rehabilitation only

ARAT improvement

184%

compared to control group (10.25 vs. 5.57 points)

Pinch strength improvement

100%

compared to control group (+1.01 kg; no meaningful change in control)

Introduction

- Single-center study at REUTH TLV Rehabilitation Hospital.
- Conducted during inpatient rehabilitation.
- Focused on post-stroke and post-TBI hand rehabilitation.

Objective

- Evaluate the safety, usability, and efficacy of Plaxtreme.
- Assess whether Plaxtreme added to standard rehabilitation improves hand function.
- Compare outcomes with standard rehabilitation alone.

Method

- **Design:** Randomized, open-label, two-arm study.
- **Groups:** Plaxtreme plus standard rehabilitation vs. standard rehabilitation only.
- **Dose:** 12 Plaxtreme treatment sessions.
- **Training:** Hand-opening and hand-closing practice with error augmentation.
- **Session time:** About 20 minutes of practice plus setup, calibration, and breaks.
- **Visits:** Baseline, interim, end of treatment, and 4-week follow-up.
- **Measures:** ARAT, Box and Block, pinch strength, grip strength, pain, Fugl-Meyer, and VAS.

Experience The Difference

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Conclusions & Key Takeaways

Conclusions

- **Nearly 200% greater ARAT improvement**: The study group improved by 10.25 points vs. 5.57 in control.
- **Clear pain advantage on VAS**: Pain decreased in the study group and increased slightly in control.
- **Device-specific functional signal**: Findings support a meaningful Plaxtreme effect on hand-specific function and pain.
- **Functional pinch range achieved**: Pinch strength increased by about 1 kg in the study group, bringing patients into the 3-5 kg range associated with functional pinch use.
- **Careful interpretation of broader tests**: Fugl-Meyer and Box and Block assess functions not directly aligned with Plaxtreme hand opening and closing training.

Key Takeaways

- Plaxtreme showed stronger ARAT improvement than standard rehabilitation alone.
- The study group showed lower pain at end of treatment, while pain increased slightly in control.
- Pinch strength improved in the study group and remained unchanged in control.
- Broader functional measures should be interpreted in the context of Plaxtreme's hand-specific treatment mechanism.

Read more about our science backed devices and our neurorehabilitation therapeutic solutions

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