Efficacy of Cerebrolysin in the reduction of Spasticity during stroke rehabilitation

Research conducted by: Department of Rehabilitation Medicine, Amang Rodriguez Memorial Medical Center (ARMMC), Marikina, Philippines

Presented & Explained by:
Ayisha Adekanmbi

Focus of Experiment:

This study aims to determine the effectiveness of Cerebrolysin in patients undergoing outpatient rehab for post-stroke: spasticity, motor recovery, and global functions.

-During this study a daily dosage of 10ml of cerebrolysin was administered over 30 days via intramuscular (shot).

Parameters of study

-30 day study
-There were two groups present: a control group who didn't receive the drug, and another group that did receive Cerebrolysin.
-50 patients used (27 control pts/ 23 pts)
-During trial patients participated in occupational therapy and physical therapy at least 2x a week for a month.

-Efficacy tested using (MAS) & (MMT) testing
-Statistical methods also utilized

Overview of results:

Patients that received the drug showed a dramatic decrease in spasticity in upper and lower limbs. Both groups showed a improvement in muscle strength and global functions.

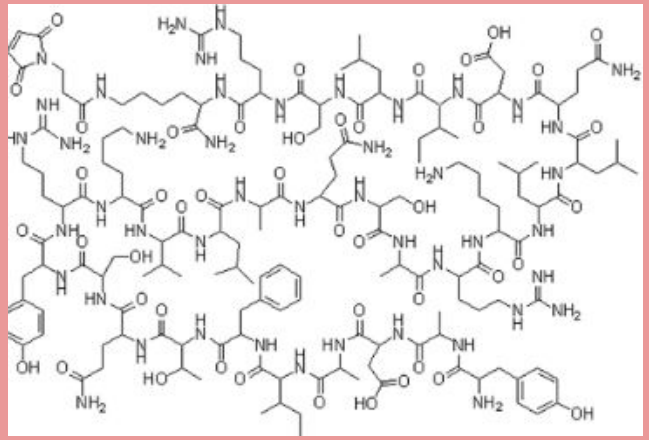
WHAT IS CEREBROLYSIN?

Cerebrolysin is a neurotrophic drug, made from a mixture of low molecular weight, porcine-derived **peptides** and **free amino acids**.

This drug aids in the brain ability to self repair by stimulating neurorecovery.

It is often used in complex treatments of acute and chronic disorders of the Central Nervous System.

Overall it helps with recovery/repair process after an injury or disease (for example stroke).



Spasticity?

Is an altered skeletal muscle performance; with a combination of paralysis, increased tendon reflex activity.

It’s characterized by an unusual tightness, stiffness, or pull of muscles

STROKE?

Stroke is a medical condition that occurs when inadequate blood flow to the brain causes cells to die.
Upon a stroke brain cell begin to die in minutes

There are two types of stroke: **Ischemic** which is due to the lack of blood flow, and **hemorrhagic** due to bleeding.

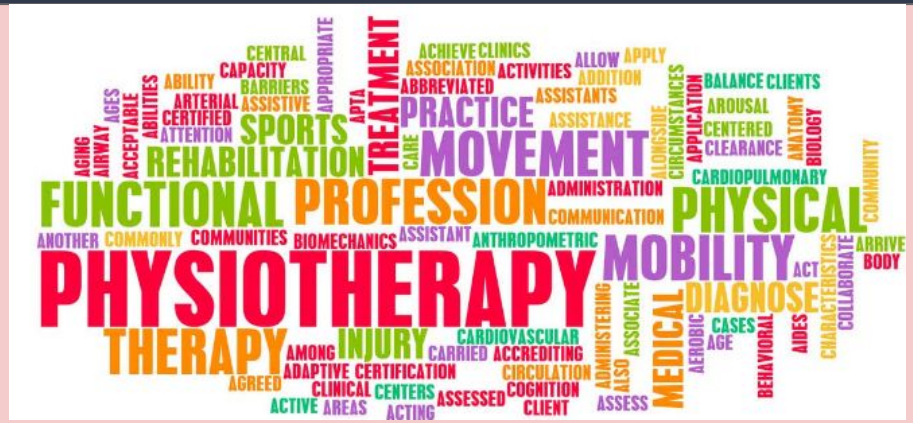
The aftermath of stroke can cause: memory loss, paralysis, vision problems, and changes in motor functions.

Occupational therapy?

Occupational therapy is a branch of therapy that helps focus on helping people perform (ADLS) Activities of daily life. Occupational therapists helps patients achieve goals and activities of daily life; by helping them grow in motor skills/ functions and in sensory development by the utilization of modifications and assessments.

Physical therapy?

Physical therapy is the treatment of a disease, illness, or injury, by physical methods. Such as: massage, heat treatment, exercise, physical examination, and diagnostic processes.


PHYSIOTHERAPY
FUNCTIONAL PROFESSION
REHABILITATION
MOVEMENT
PHYSICAL
MOBILITY
PRACTICE
SPORTS
TREATMENT
DIAGNOSE
THERAPY
INJURY
MEDICAL
CENTRAL
CAPACITY
BARRIERS
ASSISTIVE
ARTERIAL
CERTIFIED
ATTENTION
ABILITY
ABILITIES
ACCEPTABLE
AGES
AGING
AIRWAY
APPROPRIATE
APTA
ACHIEVE
CLINICS
ASSOCIATION
ABBREVIATED
ACTIVITIES
ALLOW
APPLY
ADDITION
ASSISTANTS
ASSISTANCE
CARE
ALONGSIDE
CIRCUMSTANCES
APPLICATION
BALANCE
CLIENTS
AROUSAL
CENTERED
CLEARANCE
ANATOMY
BIOLOGY
CARDIOPULMONARY
ADMINISTRATION
COMMUNICATION
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ARRIVE
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ANOTHER
COMMONLY
COMMUNITIES
BIOMECHANICS
ASSISTANT
ANTHROPOMETRIC
CHARACTERISTICS
COLLABORATE
ADMINISTERING
ALSO
ASSOCIATE
AEROBIC
CASES
AGE
BEHAVIORAL
AIDES
CARDIOVASCULAR
CARRIED
ACCREDITING
CIRCULATION
COGNITION
CLIENT
ASSESS
AMONG
ADAPTIVE
CERTIFICATION
CLINICAL
CENTERS
AGREED
ACTIVE
AREAS
ACTING
ASSESSED


OCCUPATIONAL THERAPY
Coordination
PUZZLES
Dressing
EDUCATE
TOYS
FEEDING
Self Regulation
FINE MOTOR SKILLS
MEALTIME
PLAY
Motor Planning
HANDWRKITING
playground skills
Activities of Daily Living
Routines
draw
body awareness
SENSORY PROCESSING

Methods of Experiment:

-Patients screened from an outpatient rehab clinic for post-stroke patients.
-23 cerebrolysin patients
-27 control patients
-patients participate in PT & OT 2x a week.
-Cerebrolysin admin via (IM) into deltoid, quad, or glute once daily for 30 days.
-A cold compress was placed on the injection site for 15 mins.

Patient Criteria

Patient Criteria: male and female patients above 18 years of age with ischemic or hemorrhagic stroke were included.

Patients were excluded if hemiparesis or weakness was due to an unrelated condition other than stroke

Patients were excluded if they failed to participate in physical or occupational therapy 2x a week.

Study population

Patient records from January to December 2015 were screened for patients eligible for this study according to the inclusion and exclusion criteria. Of 315 patient records screened, 50 patients were allocated either to the Cerebrolysin (N=23) or control (N=27) group. There were no significant group differences observed at baseline (**Table 1**). The mean age was slightly higher in the Cerebrolysin group (57 vs. 54 years) and male patients were more frequent (Cerebrolysin, 61%; control 88%). Most patients suffered from ischemic than hemorrhagic stroke (Cerebrolysin, 78%, control 81%) and left-sided hemiparesis (Cerebrolysin, 78%; control 52%). Time from stroke to treatment onset was slightly longer in the Cerebrolysin group (4.6 vs. 4.0 months in the controls).

Table 1. Demographic baseline characteristics

Parameter	Cerebrolysin, n=23	Control, n=27	
Male sex, n (%)	60.9	77.8	p=0.193
Mean age, y	56.6	54.3	p=0.993
Ischemic stroke, n (%)	78.3	81.5	p=0.777
Right-sided stroke, n (%)	78.3	51.9	p=0.053
Mean time since stroke, months	4.6	5.1	p=0.506

Patient Criteria

Efficacy Criteria

Utilizes:
Modified Ashworth Scale (MAS) assessment- assesses spasticity of muscles (how they flex)

-Manual Muscle Testing (MMT) assess motor recovery and muscle strength.

Modified Rankin Scale (MRS) assess global function

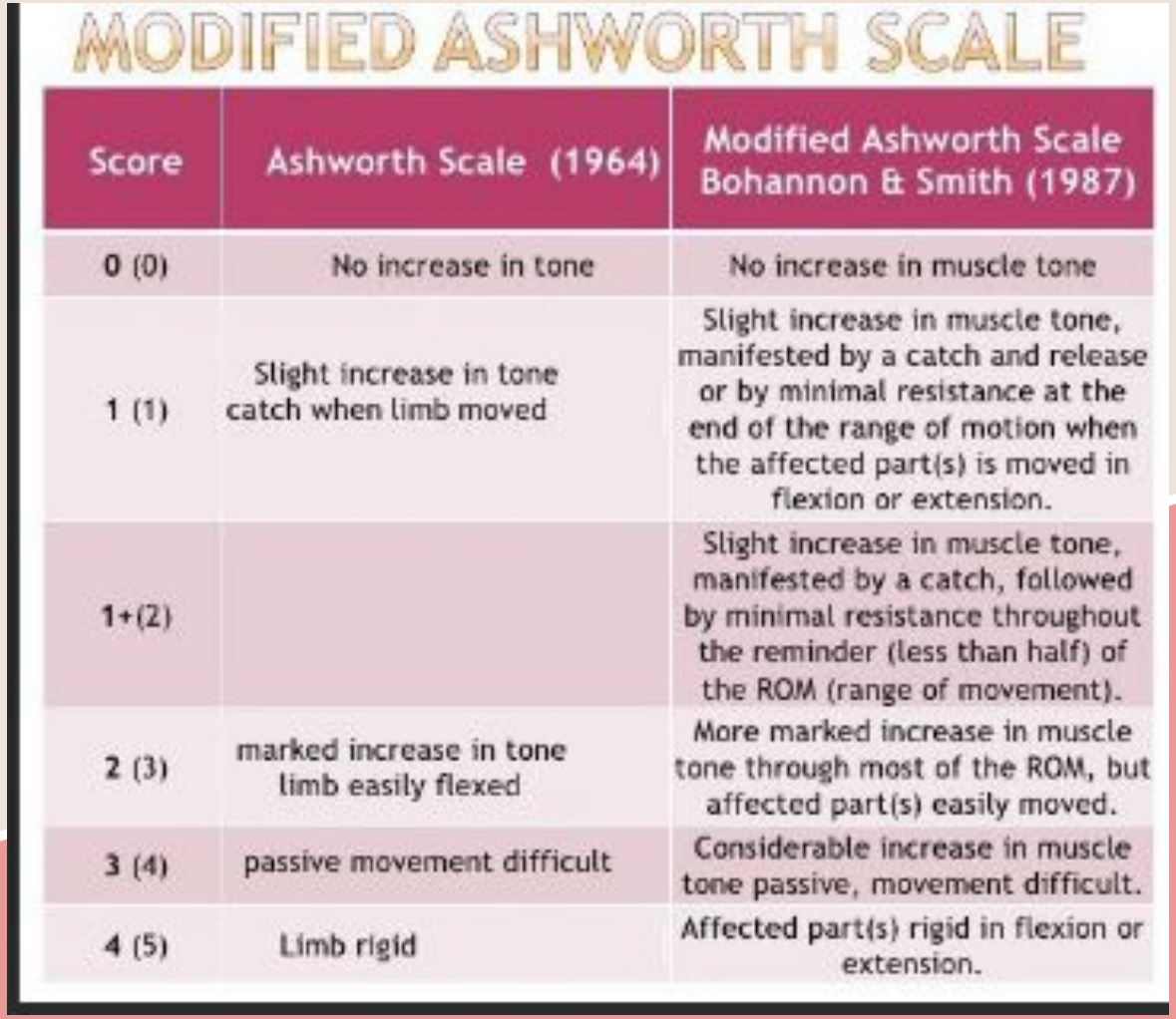
Statistical Methods

Statistics such as frequency, percentages, mean and standard deviation; were computed to determine results and demographics of the subjects.

A P-Value of 0.05 was considered statistically significant in this experiment.

Safety Criteria

Vitals signs were assessed at baseline and day 30.



Score	Ashworth Scale (1964)	Modified Ashworth Scale Bohannon & Smith (1987)
0 (0)	No increase in tone	No increase in muscle tone
1 (1)	Slight increase in tone catch when limb moved	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.
1+(2)		Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the reminder (less than half) of the ROM (range of movement).
2 (3)	marked increase in tone limb easily flexed	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved.
3 (4)	passive movement difficult	Considerable increase in muscle tone passive, movement difficult.
4 (5)	Limb rigid	Affected part(s) rigid in flexion or extension.

Modified Ashworth Scale (MAS)
(how they flex)

Grade	(%)	Qualitative value	Muscle strength
5	100	Normal	Complete range of motion (ROM) against gravity, with full resistance
4	75	Good	Complete ROM against gravity, with some resistance
3	50	Fair	Complete ROM against gravity, with no resistance
2	25	Poor	Complete ROM with a gravity omitted
1	10	Trace	Evidence of slight contractility, with no joint motion
0	0	Zero	No evidence of muscle contractility

Manual Muscle Testing (MMT) motor recovery and muscle strength.

MODIFIED RANKING SCORE	
SCORE	**DESCRIPTION**
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

Modified Rankin Scale (MRS) global function

Results Overview

Baseline scores in the (MAS) show an increase in muscle tone.

Intragroup comparison shows that patients treated with Cerebrolysin experienced a significant decrease in spasticity in all muscles of the upper and lower limbs.

In regards to the control group, muscle deterioration was present.

In regards to safety, no changes in vital signs were observed, and no adverse reactions occurred either.

In depth Analysis of Results

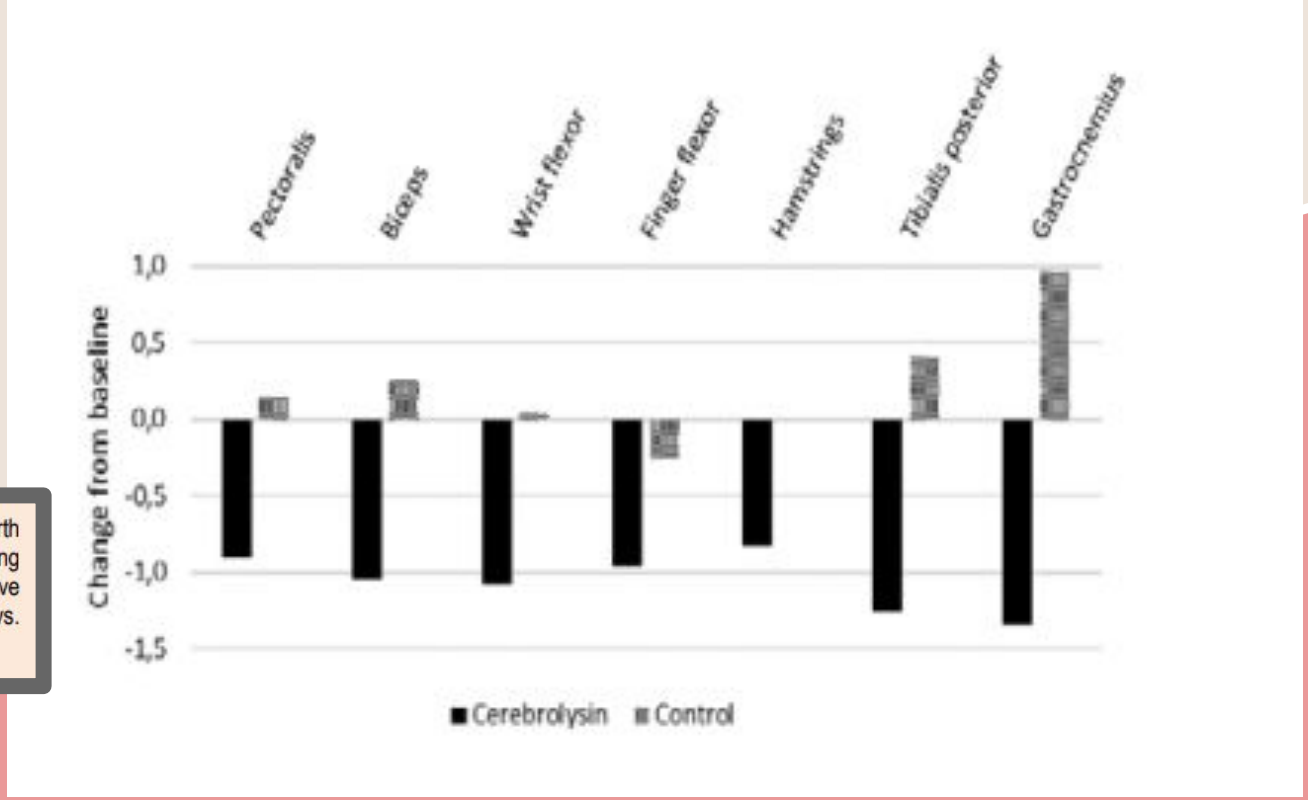


Fig. 1 Change from baseline in the Modified Ashworth Scale (MAS) at day 30 measuring spasticity by assessing resistance during passive soft-tissue stretching. Negative score differences indicate improvement. *p<0.05 vs. baseline. Cerebrolysin, n=23; control, n=27

In depth Analysis of Results

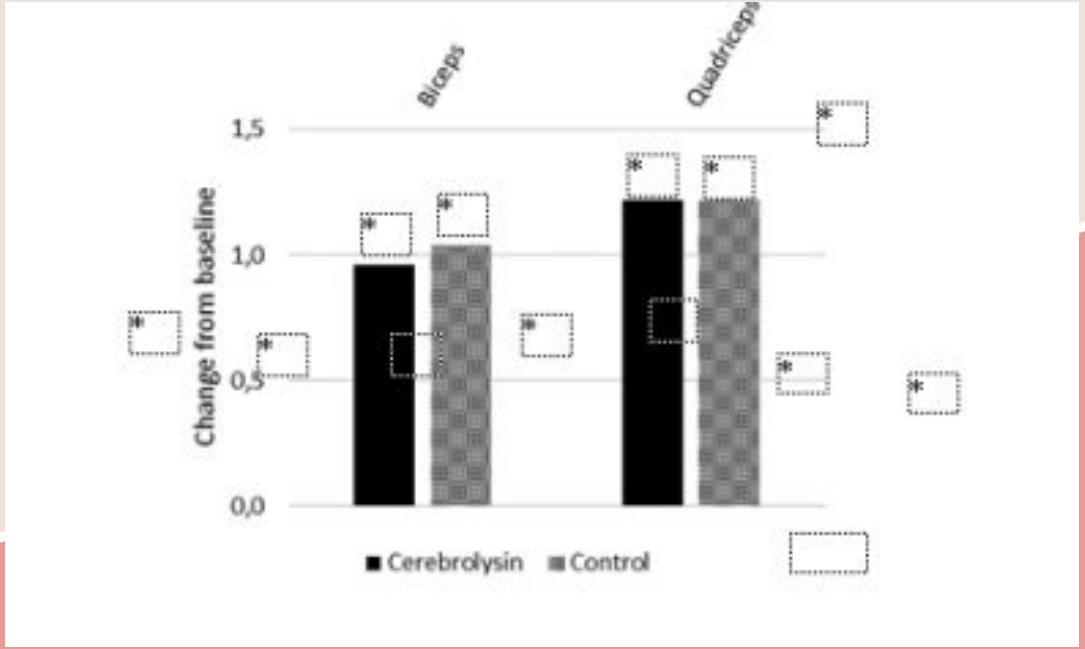
Baseline scores were comparable between study groups in the MAS showing a "more marked" or "considerable" increase in muscle tone. Intragroup comparison showed that patients treated with Cerebrolysin experienced a significant reduction of spasticity in all muscles of the upper and lower limbs as assessed by the MAS at day 30 (**Fig. 1**). Minor changes were observed in control patients showing deterioration in most muscles, which was even significant in the tibialis posterior. These changes resulted in a significant ($p<0.05$) group difference in favor of Cerebrolysin at day 30 in all muscles assessed (**Table 2**).

Table 2. Scores obtained in the Modified Ashworth Scale (MAS) and Manual Muscle Test (MMT)

	Cerebrolysin			Control			Treatment difference day 30
	Baseline	Day 30	Intragroup difference	Baseline	Day 30	Intragroup difference	
Modified Ashworth Scale							
Upper extremity							
Pectoralis	2.39±0.89	1.48±0.67	P=0.002	2.48±0.80	2.63±0.63	P=0.410	P<0.001
Biceps	2.78±0.80	1.74±0.62	P<0.001	2.67±0.55	2.93±0.73	P=0.132	P<0.001
Wrist flexor	2.65±0.93	1.57±0.73	P<0.001	2.52±0.70	2.56±0.75	P=0.868	P<0.001
Finger flexor	2.69±0.88	2.00±0.74	P<0.001	2.78±0.64	2.52±0.85	P=0.167	P=0.022
Lower extremity							
Hamstings	1.61±0.78	0.78±0.80	P<0.001	2.04±0.76	2.04±0.85	P=1.000	P<0.001
Tibialis posterior	2.83±0.83	1.57±0.79	P<0.001	2.74±0.66	3.15±0.53	P=0.016	P<0.001
Gastrocnemius	2.91±0.67	1.57±0.73	P<0.001	2.04±0.75	3.00±0.55	P=0.782	P<0.001
Manual Muscle Test							
Upper extremity							
Biceps	1.91±0.85	2.87±0.63	P<0.001	1.59±0.84	2.63±0.56	P<0.001	P=0.175
Lower extremity							
Quadriceps	1.48±0.73	2.70±0.70	P<0.001	1.89±0.85	3.11±0.42	P<0.001	P=0.015

In depth Analysis of Results

groups (**Table 2**). Improvements of muscle strength were similar in both groups (**Fig. 2**). However, at day 30, the strength of the biceps muscle was higher in the Cerebrolysin group but did not reach the level of statistical significance whereas the strength of the quadriceps muscle was in favor of the control group (**Table 2**).



Conclusion

The results show that Cerebrolysin had a beneficial effect on spasticity, improved muscle strength, and global functions; in chronic post-stroke patients in an outpatient rehabilitation setting.

Intramuscular admin of Cerebrolysin was safe and warranted no adverse effects or reactions.

Most of the findings were statistically significant regarding the P-value.

Work Cited

Martinez R. M. (2017). Efficacy of Cerebrolysin in the reduction of spasticity during stroke rehabilitation. *Journal of Medicine and Life*, *10*(3), 161–166.

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