STUDY PROTOCOL (Cover Page)

Official Title: Investigation of the Effectiveness of Diadynamic Current Therapy in Patients with Carpal Tunnel Syndrome

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Investigation of the Effectiveness of Diadynamic Current Therapy in Patients With Carpal Tunnel Syndrome

1. Background and Rationale

Carpal tunnel syndrome (CTS), first described by Paget in 1854, is the most common entrapment neuropathy of the upper extremity. It results from compression of the median nerve within the carpal tunnel and is characterized by pain, numbness, tingling, and functional impairment of the hand. In patients with mild to moderate CTS, conservative, non-surgical treatment approaches are preferred as the first-line therapy.

Conservative treatment options include patient education, tendon and median nerve gliding exercises, splint use, physical therapy modalities, kinesiotaping, manual therapy techniques, injection therapies, and oral medical treatments. Initial treatment typically consists of patient education, exercise programs, and the use of wrist splints that maintain the wrist in a neutral position.

Tendon and median nerve gliding exercises play an important role in the conservative management of CTS. Randomized controlled studies have demonstrated that these exercises contribute to symptom reduction and functional improvement. Splint use is recommended at all stages of CTS, with night-time neutral-position wrist splints being the most commonly preferred option.

Diadynamic currents (DDC) are thought to have a composite analgesic mechanism primarily explained by the gate control theory. It is suggested that DDC affects both sensory and motor nerves and may increase endorphin release, thereby producing an analgesic effect. Some studies have reported that the analgesic effectiveness of DDC may be greater than that of transcutaneous electrical nerve stimulation (TENS). Although TENS is more commonly used in physical therapy practice, DDC may represent a realistic alternative for clinical pain management.

2. Study Objectives

The primary objective of this study is to evaluate the effects of diadynamic current therapy on clinical symptoms in patients diagnosed with carpal tunnel syndrome.

The secondary objective is to investigate the effects of diadynamic current therapy on electrophysiological findings of the median nerve.

3. Study Population

3.1 Inclusion Criteria

1. Clinically and electrophysiologically diagnosed with carpal tunnel syndrome
2. Voluntary participation with written informed consent
3. Aged between 18 and 65 years

3.2 Exclusion Criteria

1. Age below 18 or above 65 years
2. Median nerve distal motor latency longer than 6.0 ms on nerve conduction studies (NCS)
3. Presence of thenar muscle atrophy
4. History of surgery for carpal tunnel syndrome
5. History of steroid injection into the carpal tunnel
6. History of physical therapy for CTS within the last 6 months
7. Presence of cervical radiculopathy
8. Tenosynovitis in the ipsilateral upper extremity
9. Another compressive neuropathy in the ipsilateral upper extremity
10. Peripheral polyneuropathy
11. History of trauma or fracture involving the hand, wrist, or forearm
12. Active pregnancy
13. Presence of metabolic disease
14. Inflammatory rheumatic disease
15. Acute and/or chronic renal failure
16. Severe cognitive impairment preventing understanding and following simple instructions
17. Severe visual or hearing impairment preventing participation in treatment
18. Current use of pregabalin or gabapentin
19. Presence of systemic diseases (e.g., diabetes mellitus, hypothyroidism, rheumatic diseases)

4. Study Design and Methods

This prospective controlled study is planned to be conducted between **April 15, 2025, and October 15, 2025**, at the Department of Physical Medicine and Rehabilitation, Duzce University Faculty of Medicine Research and Application Hospital.

Demographic data including age, sex, height, weight, dominant hand, marital status, educational level, occupation, and duration of employment will be recorded. Information regarding the affected hand, type and duration of symptoms, daily symptom patterns,

comorbid diseases, history of trauma or surgery, previous CTS treatments within the last six months, smoking and alcohol use, and pregnancy status will be collected.

Patients clinically diagnosed with CTS will routinely undergo nerve conduction studies (NCS) at the Electromyography Laboratory of the Department of Neurology, Duzce University Faculty of Medicine. Patients with electrophysiological findings consistent with mild to moderate CTS will be included in the study.

5. Study Groups and Interventions

Participants will be allocated into two groups:

Group	Exercise Program	Splint Use	Additional Treatment
DDC Group	Home program	Night-time	Diadynamic current (10 sessions)
Control Group	Home program	Night-time	None

All participants will receive patient education and written and visual instructions on tendon and median nerve gliding exercises. Both groups will be instructed to perform the exercises daily for 12 weeks, consisting of 6 sets (30 repetitions) per day.

5.1 Diadynamic Current (DDC) Application

Diadynamic current therapy will be applied to the palmar surface of the hand and the volar surface of the forearm using 6 × 6 cm carbon electrodes as follows:

- Diphase fixe (DF): 2 minutes
- Monophase fixe (MF): 3 minutes
- Longues periodes (LP): 3 minutes
- Courtes periodes (CP): 2 minutes

Total application time will be 10 minutes. The treatment parameters and sequence will be based on Bernard's current methodology.

5.2 Splint Application

Both groups will be provided with a resting wrist splint maintaining the wrist in a neutral position. Participants will be instructed to wear the splint every night before bedtime and remove it in the morning.

6. Outcome Measures and Follow-up

Participants will be evaluated twice: at baseline (pre-treatment) and at the 6th week of treatment.

Outcome Measures

Parameter	Assessment Method
Pain and numbness	Visual Analog Scale (VAS), BCTQ-SSS

Functional status	BCTQ-FSS
Hand grip strength	Hand dynamometer
Pinch strength	Pinch meter
Median nerve involvement	Nerve conduction studies (NCS)

BCTQ-SSS: Boston Carpal Tunnel Questionnaire – Symptom Severity Scale

BCTQ-FSS: Boston Carpal Tunnel Questionnaire – Functional Status Scale

7. Concomitant Medication

During the study period, except on assessment days, participants will be allowed to use paracetamol for pain relief when necessary, with a maximum dose of 1 g/day.

8. Ethical Considerations and Safety

This study will be conducted in accordance with the principles of the Declaration of Helsinki. Approval was obtained from the Düzce University Non-Interventional Health Research Ethics Committee on 24 March 2025, Decision No. 2025/69. Written informed consent will be obtained from all participants prior to enrollment.