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The effectiveness of splinting for the treatment of carpal tunnel syndrome

Submission date
01/11/2022

Recruitment status
No longer recruiting

Registration date
02/11/2022

Overall study status
Completed

Last Edited
30/11/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Carpal tunnel syndrome (CTS) is among the most frequent nerve disorders of the arm. Occupational therapists typically treat CTS conservatively by splinting the wrist, but the success of this treatment is not well-researched. The aim of this study is to evaluate the effectiveness of splinting the wrist with a modified splint which supports the wrist and the fingers, in the treatment of carpal tunnel syndrome.

Who can participate?
Patients aged 18 years and over with carpal tunnel syndrome

What does the study involve?
This study involves basic measurements before and after the use of the splint. An occupational therapist will assess the hand's strength, sensation, and movement, and then will fit the hand with a splint to support the wrist and fingers for 6 weeks to relieve the symptoms of the condition.

What are the possible benefits and risks of participating?
The study will help us understand if splinting the wrist and fingers is effective in treating carpal tunnel syndrome. The treatment is conservative, and no harm or unintended effects are foreseen. Confidentiality is assured, and all the information gathered in this study will be kept with the researcher.

Where is the study run from?
Kuwait University (Kuwait)

When is the study starting and how long is it expected to run for?
January 2018 to February 2023

Who is funding the study?
Kuwait University (Kuwait)

Who is the main contact?
Dr Mohammed Sh. Nadar, mohammed.nadar@ku.edu.kw

Contact information

Type(s)
Principal Investigator

Contact name
Dr Mohammed Nadar

ORCID ID
https://orcid.org/0000-0003-4281-5630

Contact details
Occupational Therapy Department
Faculty of Allied Health Sciences
Kuwait University
Jabriah
Kuwait
00000
+965 (0)24633491
mohammed.nadar@ku.edu.kw

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy of splinting the wrist and metacarpophalangeal joints for the treatment of carpal tunnel syndrome

Study objectives
The purpose of this assessor-blinded study is to compare the effectiveness of traditional cock-up splints (which restrict the wrist in neutral) with customized splints (which restrict the wrist and the metacarpophalangeal [MCP] joints of the medial four digits in neutral) in the treatment of mild-to-moderate carpal tunnel syndrome. The hypotheses are: (1) the splinting treatment will

reduce CTS symptoms and improve functional status in patients with mild-to-moderate CTS in both groups; and (2) the group that receives the splint that supports the wrist and MCP will show better outcome (i.e., more reduction in symptom severity and more improvement in functional status) than the group that will receive the traditional wrist cock-up splint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2018, Health Sciences Center Ethical Committee - Kuwait University (Centre for Research Support & Conferences, Office of the Vice Dean for Research & Postgraduate Studies, HSC, Faculty of Medicine, PO Box 24923, Safat 13110, Kuwait; +965 (0)24634524; hsc.ethicalcommitee@ku.edu.kw), ref: VDR/EC/3410

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Carpal tunnel syndrome

Interventions
The study includes 60 participants with mild to moderate carpal tunnel syndrome. A simple randomization procedure of computer-generated random numbers is used to randomize the participants into two groups: an experimental group that is fitted with an MCP splint to support the wrist and MCP joints (the splint will position the wrist in neutral (0°) and the MCP joints in 20° of flexion), and a control group that will receive a traditional wrist splint, which will be fabricated to support the wrist in neutral (0°) position and with no finger restrictions. Both groups will follow the same treatment plan and wearing schedule. All the participants will be instructed to wear splints all day and night for 4 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Metacarpophalangeal (MCP) splint, MCP joints, traditional wrist splint

Primary outcome measure
1. Symptoms severity and functional status measured using the Levine-Katz (Boston) Carpal Tunnel Syndrome Questionnaire at baseline, 6 weeks, and 3 months
2. Grip strength measured using hand-held dynamometer at baseline, 6 weeks, and 3 months
3. Two-point discrimination sensation measured using the Disk-Criminator tool at baseline, 6 weeks, and 3 months
4. Touch sensibility threshold measured using Semmes Weinstein monofilaments at baseline, 6 weeks, and 3 months

Secondary outcome measures
Tingling sensation measured using the Phalen's test and the Tinel's sign test at baseline, 6 weeks, and 3 months

Overall study start date
10/01/2018

Completion date
20/02/2023

Eligibility

Key inclusion criteria
Adults (aged 18 years and over) with confirmed diagnoses of mild to moderate CTS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Neuropathy (e.g., diabetes mellitus or thyroid disease) other than CTS in the past year
2. Pregnancy
3. Had a steroid injection into the carpal canal in the past 3 months
4. Receive a steroid injection during the time of the study

Date of first enrolment

05/11/2022

Date of final enrolment
05/02/2023

Locations

Countries of recruitment
Kuwait

Study participating centre
Kuwait University
Faculty of Allied Health Sciences
Fourth Ring Rd
Jabriya
Kuwait
00000

Sponsor information

Organisation
Kuwait University

Sponsor details
4th Ring Road
Jabriah
Kuwait
00000
+965 (0)24633489
naser.alotaibi@ku.edu.kw

Sponsor type
University/education

Website
http://www.kuniv.edu/ku

ROR
https://ror.org/021e5j056

Funder(s)

Funder type

University/education

Funder Name
Kuwait University

Alternative Name(s)
KU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Kuwait

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from the first author (Mohammed Nadar, mohammed.nadar@ku.edu.kw)
The type of data that will be shared: raw data in Excel or SPSS
Timing for availability: after study completion (estimated time is March 2023)
Whether consent from participants was required and obtained: Yes, consent is required and will be obtained from all participants.
Comments on data anonymization: The data is anonymous, and will not contain identifying information of participants
Any ethical or legal restrictions: Ethical approval was obtained. The data to be shared has no ethical or legal restrictions

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2023	30/11/2023	Yes	No