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Effectiveness of low-level electric current water bath on subjects with chronic non-specific neck pain

Submission date
01/02/2020

Recruitment status
No longer recruiting

Registration date
05/02/2020

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Neck pain is one of the world's leading causes for the years lived with disability. Ambiguity in the effect of electrotherapy modalities for the treatment of Chronic Non-Specific Neck Pains (CNSNP) needs to be studied further.
A number of treatments are widely prescribed for chronic pain syndromes and are not fully effective. In clinical practice, the effectiveness of electrotherapy is limited in particular to hydro galvanic bath therapy in the management of chronic pain syndromes, which needs to be evaluated.
Aim: This study aims to evaluate whether hydro galvanic therapy can be beneficial in decreasing pain, pain pressure threshold and increasing quality of life in subjects with chronic nonspecific neck pain.

Who can participate?
Patients aged 18 years or above with chronic non-specific neck pain.

What does the study involve?
Subjects will be divided at random into to study group and the control group. The subjects in the study group will receive a hydro-galvanic bath along with exercises and control group subjects will receive Trans-cutaneous Electrical Nerve Stimulation (TENS) along with exercises for 4 sessions per week for 12 weeks.

What are the possible benefits and risks of participating?
The subjects will be getting 12 weeks of hydrogalvanic bath treatment without any cost. Along with this, they will be getting free consultation, assessment and exercise programs from experienced therapists. There is no risk involved due to our treatment it is absolutely safe for them.

Where is the study run from?
King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
February 2019 to May 2020

Who is funding the study?
King Khalid University (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HA-06-B-001

Study information

Scientific Title
Effectiveness of hydro galvanic bath on improving pain, disability and quality of life in subjects with chronic non-specific neck pain: a randomized control trial

Study objectives
The hydro galvanic bath will be effective in improving pain, disability and quality of life in subjects with chronic non-specific neck pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2019, The scientific research ethics committee of King Khalid University (Deanship of Scientific Research, 3rd floor, Building D, King Khalid University, Guraiger, Abha - 61481, Kingdom of Saudi Arabia; +966 17 2418336; ecm@kku.edu.sa), ref: HA-06-B-001

Study design
Interventional 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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic non-specific neck pain

Interventions
The subjects will be divided into to study group and the control group by block randomization.

The subjects in the study group will receive a hydro-galvanic bath along with exercises. Control group subjects will receive Trans-cutaneous Electrical Nerve Stimulation (TENS) along with exercises for 4 sessions per week for 12 weeks.

Outcome measures: Pain by Visual Analog Scale (VAS), Disability by Neck Disability Index, and Quality of Life by Short form 36 (SF-36) will be evaluated pre and post 12 weeks intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hydro galvanic bath

Primary outcome measure

Pre and post 12 weeks intervention:
1. Pain with Visual Analog Scale (VAS)
2. Disability with Neck Disability Index (NDI)
3. Quality of life with Short Form-36 (SF-36)

Secondary outcome measures
Age at disease onset

Overall study start date
11/02/2019

Completion date
11/05/2020

Eligibility

Key inclusion criteria
Chronic non-specific neck pain

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
34

Total final enrolment
34

Key exclusion criteria
1. Malignancy
2. Neurological issues
3. Headaches with a specific diagnosis
4. Trauma
5. Infections
6. Skin cuts on upper limbs

Date of first enrolment
25/02/2019

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid University
Physical Therapy Out-Patient Clinic
Gate 5, Building C
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Sponsor information

Organisation
King Khalid University

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Sponsor type
University/education

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ROR
https://ror.org/052kwzs30

Funder(s)

Funder type
University/education

Funder Name
King Khalid University

Alternative Name(s)
, KKU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Upon the completion of the study, it will be published in the peer-reviewed journal.

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/10/2020	22/10/2020	Yes	No