

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	<input type="checkbox"/> Prospectively registered
Registration date 05/02/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/10/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?
Dr Jaya Shanker Tedla
jtedla@kku.edu.sa

Contact information

Type(s)
Public

Contact name
Dr Jaya Shanker Tedla

Contact details
C/3/108, Guraiger
King Khalid University
Abha
Saudi Arabia
61421
+966 (0)538901083
jtedla@kku.edu.sa

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

Age at disease onset

Completion date

11/05/2020

Eligibility

Key inclusion criteria

Chronic non-specific neck pain

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Guraiger

Abha

Saudi Arabia

61421

Sponsor information

Organisation

King Khalid University

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

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