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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>			
01/02/2020		☐ Protocol			
Registration date 05/02/2020	Overall study status Completed	Statistical analysis plan			
		[X] Results			
<b>Last Edited</b> 22/10/2020	Condition category  Musculoskeletal Diseases	Individual participant data			
/// 10//0/0	Musculoskeletai Diseases				

#### 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

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# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes