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New photogrammetric instrument for evaluating the cervical spine range of motion: clinical validity and gender study

Submission date
12/08/2024

Recruitment status
No longer recruiting

Registration date
05/09/2024

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Neck pain and other issues related to the cervical spine are common problems that can significantly affect people's lives. Diagnosing and treating these conditions often require precise measurements of neck movement. This study focuses on the development and validation of a new instrument called RomIX, which is designed to measure the motion of the cervical spine accurately, which includes a comparison of its performance regarding reliability and validity with existing goniometry.

Who can participate?
Healthy adults 18 - 60 years old

What does the study involve?
Participants are involved to calibrate the instrument and establish a normative standard range-of-motion value for healthy individuals. Participants in the study had their neck movements measured using the RomIX in six directions (flexion, extension, right/left side bending, and right /left rotation). The data were compared with manual goniometric results to examine its accuracy.

What are the possible benefits and risks of participating?
Participants in this study can contribute to the development of a new medical device that could improve the diagnosis and treatment of neck problems. RomIX could be particularly useful for healthcare professionals in diagnosing and treating neck-related issues, offering a non-invasive, accurate, and user-friendly method for assessing cervical spine motion.

Where is the study run from?
Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases, Vietnam

When is the study starting and how long is it expected to run for?
May 2023 to September 2024

Who is funding the study?
Korea International Cooperation Agency (KOICA) (South Korea)

Who is the main contact?
Mr. Minh Nguyen Huu Duc (MD in Traditional Medicine, University of Medicine and Pharmacy at Ho Chi Minh City), nhdminh@ump.edu.vn

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
No. 2021-00020-3

Study information

Scientific Title
Novel photogrammetric instrument to measure the cervical range of motion: validity and gender-based assessment in a clinical study

Study objectives
This study aims to examine the reliability and validity of the RomIX, a photogrammetric scanner instrument, to measure cervical range of motion (ROM) compared with manual goniometry.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/07/2023, Ethics committee of University of Medicine and Pharmacy at Ho Chi Minh City (217 Hong Bang Street, Ward 11, District 5, Ho Chi Minh City, 748000, Viet Nam; +84 (0) 2838558411; hanhchinh@ump.edu.vn), ref: No. 704/HDDD-DHYD

2. Approved 27/07/2023, Ethics committee of Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases (313 Au Duong Lan Street, Ward 2, District 8, Ho Chi Minh City, 751000, Viet Nam; +84 (0)2838569147; bvphcn.syt@tphcm.gov.vn), ref: No. 16/HDDD-BVPHCN-DTBNN

Study design
Single-centre cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Evaluation of the cervical range of motion on healthy individuals using a photogrammetric instrument as fundamental for cervical spondylosis screening and diagnosis

Interventions
Current interventions:
530 enrolled participants underwent the measurement sessions, where their neck range of motion in six directions (flexion, extension, right/left side bending, right/left rotation) was recorded using manual goniometry and the photogrammetric instrument. Each participant was examined using both methods, with the total duration of involvement being 15 minutes. The total duration of observation is 1 week, with a follow-up period of 2 weeks.

Previous interventions:
50 enrolled participants underwent the measurement sessions, where their neck range of motion in six directions (flexion, extension, right/left side bending, right/left rotation) was recorded using manual goniometry and the photogrammetric instrument. Each participant was examined by both methods, respectively, with the total duration of involvement being 15 minutes. The total duration of observation is 1 week, with a follow-up period of 2 weeks.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
RomIX (photogrammetric instrument)

Primary outcome measure
Cervical spine range of motion measured in six directions (flexion, extension, right/left side bending, right/left rotation) by goniometry and the the photogrammetric instrument at baseline

Secondary outcome measures
Intraclass correlation (ICC), standard error of measurement (SEM), minimal detectable change (MDC), and Pearson’s correlation coefficient (r) calculated from neck range-of-motion at baseline

Overall study start date
01/05/2023

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Participants are 18 years of age or older, regardless of gender or occupation.
2. Participants are capable of performing normal studying or working activities.
3. Participants have full cognitive and behavioral capacity.
4. Participants voluntarily agree to participate in the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
530

Total final enrolment
530

Key exclusion criteria
1. Participants report or complain of neck, shoulder and/or headache pain in the previous month.
2. Participants have history of neck and/or shoulder disorders, including trauma and fractures, history of neurological and/or rheumatic disorders.
3. Participants have history of other relevant medical conditions.

Date of first enrolment
01/06/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
Viet Nam

Study participating centre
Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases
313 Au Duong Lan Street, Ward 2, District 8
Ho Chi Minh City
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751000

Sponsor information

Organisation
University of Medicine and Pharmacy at Ho Chi Minh City

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Sponsor type
University/education

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Funder(s)

Funder type
Government

Funder Name
Korea International Cooperation Agency

Alternative Name(s)
KOICA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

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

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author (Mr Minh Nguyen Huu Duc, nhdminh@ump.edu.vn)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			05/09/2024	No	Yes
Participant information sheet			09/09/2024	No	Yes
Other files	Basic results (Phase 1 only)	09/10/2024	09/10/2024	No	No