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New camera-based instrument to measure neck movement: its validity and sex differences in healthy adults

Submission date
12/08/2024

Recruitment status
No longer recruiting

Registration date
05/09/2024

Overall study status
Completed

Last Edited
28/10/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Neck pain is a common musculoskeletal problem that can limit daily activities and cause substantial healthcare costs. Accurate measurement of neck motion is essential for diagnosis and rehabilitation. This study aimed to evaluate RomIX, a new photogrammetric instrument developed by the research team to measure cervical spine motion objectively and automatically. The study examined how reliable and valid RomIX is compared with the standard manual goniometer and also explored differences in neck mobility between male and female.

Who can participate?
Healthy adults aged 18 years or older with no history of neck or shoulder disorders, no pain (VAS = 0), and minimal neck disability (NDI ≤ 4).

What does the study involve?
Participants stood in the RomIX system and performed six active neck movements: flexion, extension, right and left side bending, and right and left rotation. Each movement was held for five seconds. The same participants were also measured using a manual digital goniometer by two independent clinicians. The results from both methods were compared to test RomIX's reliability and validity. A larger group of 480 asymptomatic adults was assessed using RomIX to establish normative reference data and investigate sex-based differences in cervical motion.

What are the possible benefits and risks of participating?
Participants contributed to validating a new instrument that may help clinicians assess neck function more accurately and efficiently. The procedure was non-invasive and safe, with no adverse effects reported. RomIX may provide a faster, marker-free, and more objective method for cervical motion assessment in clinical and rehabilitation settings.

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) under the project “Education and Research Capacity Building Project at University of Medicine and Pharmacy at Ho Chi Minh City” (Project No. 2021-00020-3).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
No. 2021-00020-3

Study information

Scientific Title
Novel photogrammetric instrument to measure cervical spine range of motion: test-retest reliability, construct validity, and sex-based assessment through a cross-sectional study on asymptomatic adults

Study objectives

Current Study objectives as of 27/10/2025:

To examine test-retest reliability, construct validity, and measurement error of RomIX, a photogrammetric instrument developed by the authors, to measure active cervical spine range of motion (CROM) compared to manual goniometry.

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Previous 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
Cross-sectional observational clinimetric study"

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Evaluation of active cervical spine range of motion in asymptomatic adults using a novel photogrammetric instrument as foundation for cervical spondylosis screening and diagnosis

Interventions
Current interventions as of 27/10/2025:

A total of 530 asymptomatic adults participated in the measurement sessions assessing active cervical spine range of motion in six directions: flexion, extension, right and left side bending, and right and left rotation. Measurements were performed in standing position using both manual digital goniometry and the RomIX photogrammetric instrument.

For RomIX, each participant stood at the center of the instrument and performed maximal active neck movements in each direction, holding for 5 seconds per movement. A single rater recorded all directions three times under identical conditions to determine test-retest reliability. The full RomIX procedure lasted approximately 5 minutes, with a 5-minute rest between repetitions. For manual goniometry, two independent clinicians performed all assessments following

standardized protocols for flexion/extension, side bending, and rotation. Inter-rater reliability was evaluated by comparing results between the two clinicians, who were blinded to each other' s data. Each goniometric session took about 10 minutes, with a 5-minute break between repetitions.
All conditions, including participant posture, device alignment, and measurement environment, were standardized to ensure reproducibility and to minimize measurement error.

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Previous interventions as of 09/09/2024:

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

Phase
Phase II/III

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

Primary outcome(s)
Current primary outcome measure as of 27/10/2025:

Active cervical spine range of motion in six directions (flexion, extension, right/left side bending, right/left rotation) by manual goniometry and the RomIX photogrammetric instrument at baseline

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Previous 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

Key secondary outcome(s))
Current secondary outcome measures as of 27/10/2025:

Intraclass correlation coefficient (ICC), standard error of measurement (SEM), minimal detectable change (MDC), and Pearson’s correlation coefficient (r) from active cervical spine range of motion at baseline

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Previous 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

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 27/10/2025:

Eligibility criteria for participants were adults aged 18 years or older, regardless of sex or occupation, who were actively participating in study, work, and normal daily activities. Inclusion criteria required that participants had a Visual Analog Scale (VAS) pain score of 0, a Neck Disability Index (NDI) score of ≤ 4, full cognitive and behavioral awareness, and voluntary agreement to participate.

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Previous 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
530

Key exclusion criteria
Current key exclusion criteria as of 27/10/2025:

Exclusion criteria included current or recent neck, shoulder, and/or headache symptoms within the previous 3 months; history of cervical spine or shoulder disorders; neurological and/or rheumatic conditions; and symptoms of nerve compression or radiculopathy.

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Previous 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, Chanh Hung Ward
Ho Chi Minh City
Viet Nam
751000

Sponsor information

Organisation
University of Medicine and Pharmacy at Ho Chi Minh City

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

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 (Dr Nguyen Huu Duc Minh, nhdminh@ump.edu.vn)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			28/10/2025	Yes	No
Dataset			28/10/2025	No	No
Other files	Basic results (Phase 1 only)	09/10/2024	09/10/2024	No	No
Participant information sheet			05/09/2024	No	Yes
Participant information sheet			09/09/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes