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Do patients with shoulder complaints need a cervical assessment?

Submission date
23/04/2025

Recruitment status
No longer recruiting

Registration date
24/04/2025

Overall study status
Completed

Last Edited
24/04/2025

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
Shoulder pain is frequently assessed using standard clinical tests that help determine the most appropriate treatment. However, in clinical practice, it is sometimes observed that the results of these shoulder tests change after a neck and upper back (cervical-thoracic) assessment, even when patients report no symptoms in those areas. This raises an important question: Could spinal involvement influence shoulder test outcomes, and if so, should the spine be routinely assessed in these cases?
This study uses Mechanical Diagnosis and Therapy (MDT), a structured physiotherapy assessment approach, to explore that question. The aim is to observe whether the results of commonly used shoulder tests change immediately after a cervical-thoracic spine assessment and, if indicated, treatment, in people with shoulder pain who report no neck or upper back symptoms.

Who can participate?
Adults aged 18 years and older with shoulder pain as their primary complaint can participate. People are only included if their pain is localized to the shoulder (e.g., in the deltoid area) and if they do not have any neck or upper back symptoms. Participants must be able to complete physiotherapy tests and questionnaires in Dutch. People with serious injuries, recent surgery, or neck-related nerve symptoms are excluded.

What does the study involve?
Participants attend a physiotherapy clinic for a structured, single-day assessment. First, they complete a set of standardized questionnaires measuring shoulder function, general health, and neck-related disability: the Shoulder Pain and Disability Index (SPADI), Simple Shoulder Test (SST), RAND-36 Health Survey, and Neck Disability Index (NDI). These questionnaires help determine eligibility and establish a functional baseline.
Following this, one physiotherapist (the first examiner) performs five standard clinical shoulder tests: the Neer test, Hawkins-Kennedy test, Jobe test (Empty Can), active shoulder abduction, and the Hand-to-Scapula (HTS) test. Pain during these tests is recorded using a Numeric Pain Rating Scale (0–10), and shoulder movement (particularly abduction) is measured using a goniometer.
After the shoulder tests, a second, independent physiotherapist certified in Mechanical

Diagnosis and Therapy (MDT) performs a mechanical assessment of the cervical and upper thoracic spine. This includes repeated end-range movements and postures to identify the presence or absence of a directional preference, which classifies participants into either a Cervical Derangement (CD) group or Cervical Non-Derangement (CND) group.
If a cervical derangement is identified, a short MDT-based treatment is delivered immediately during the same session.
Finally, the original examiner, still blinded to the classification and intervention, repeats the same five shoulder tests to determine whether test results or symptoms have changed after the cervical-thoracic intervention. The entire study procedure is completed in one session lasting no longer than 60 minutes.

What are the possible benefits and risks of participating?
Participants may experience a quick reduction in their shoulder symptoms if the neck or upper back contributes to the problem. They also benefit from a thorough examination and expert physiotherapy care. An additional benefit is that the study raises awareness about the importance of not overlooking the cervical and thoracic spine in assessing shoulder pain, even when no spinal symptoms are reported.
There are no known risks beyond mild discomfort during movement testing, common in routine physiotherapy assessments. No medications or injections are involved.

Where is the study run from?
The study is coordinated by the Department of Rehabilitation Sciences at KU Leuven (Belgium) and takes place across five independent physiotherapy clinics in the Dutch-speaking region of Belgium.

When is the study starting and how long is it expected to run for?
The study began with planning in January 2016. Recruitment of participants took place between 26 September 2016 and 26 April 2017. Data collection was completed in April 2017.

Who is funding the study?
Investigator initiated and funded

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
Not applicable

Study information

Scientific Title
Do patients with localized shoulder pain benefit from cervical-thoracic spine assessment? A mechanical diagnosis and therapy-based prospective cohort study

Acronym
C-SHOULD

Study objectives
In patients presenting with localized shoulder pain and no cervical-thoracic symptoms, one or more positive clinical shoulder tests will become significantly less painful and/or functionally improved immediately after Mechanical Diagnosis and Therapy (MDT) assessment and intervention targeting the cervical-thoracic spine, but only in those classified with a reducible cervical derangement.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 05/07/2016, University of Dundee Research Ethics Committee (Dundee, Dundee, DD1 4HN, United Kingdom; +44 (0)1382229993; psych@dundee.ac.uk), ref: UREC 16081

2. approved 21/10/2016, Commissie Medisch Ethiek (UZ gasthuisberg Herestraat 49, Leuven, 3000, Belgium; +32 (0)16 348600; ec@uzleuven.be), ref: B322201629931

Study design
Prospective single-group test-retest study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied

Localized shoulder pain

Interventions

This was a prospective, single-group, test-retest study conducted in five outpatient physiotherapy clinics in Belgium. The study aimed to explore the immediate effects of a Mechanical Diagnosis and Therapy (MDT) assessment of the cervical-thoracic spine on clinical shoulder tests in patients presenting with localized shoulder pain and no symptoms in the cervical-thoracic region.

The study focused on adults with localized shoulder pain as their primary complaint. Participants had no symptoms in the cervical-thoracic spine region and did not show signs of cervical radiculopathy or structural shoulder pathology. The population targeted represents a common clinical subgroup frequently encountered in outpatient physiotherapy settings — patients with shoulder complaints that cervical-thoracic mechanical factors may influence despite the absence of neck symptoms.

Participants first underwent a baseline assessment involving a standardized set of five shoulder clinical tests. Then, a second blinded examiner performed a cervical MDT assessment to classify patients as having a Cervical Derangement (CD) or a Cervical Non-Derangement (CND) based on MDT principles. If a CD was confirmed, a full MDT treatment session was conducted during the same visit.

The intervention consisted of a Mechanical Diagnosis and Therapy (MDT) assessment and, when indicated, treatment of the cervical-thoracic spine. The MDT assessment involved repeated end-range neck and upper thoracic movements and sustained postures to identify a directional preference (DP) and classify participants into one of two categories:
Cervical Derangement (CD): if a DP was present with or without centralization of symptoms.
Cervical Non-Derangement (CND): if no DP or centralization response was identified.

When a CD was confirmed, the therapist applied MDT treatment strategies within the same session. This included repeated movements in the identified direction of preference and, if needed, progression to therapist-applied techniques (e.g., mobilizations) aimed at reducing the derangement.

The intervention was delivered by physiotherapists credentialed or diploma-holding in MDT, each with a minimum of 10 years of clinical experience. All procedures were standardized and preceded by training to ensure consistency across examiners and clinics.

Participants first underwent a baseline clinical assessment, which included:
Completion of standardized questionnaires:
Neck Disability Index (NDI) – to screen for neck-related disability.
Shoulder Pain and Disability Index (SPADI) and Simple Shoulder Test (SST) – to assess shoulder function.
RAND-36 – to evaluate health-related quality of life.

Performance of five standardized clinical shoulder tests, selected for their clinical relevance and reliability:
1. Hawkins-Kennedy Test
2. Neer Test
3. Jobe’s Test (Empty Can)
4. Active Shoulder Abduction Test
5. Hand-to-Scapula (HTS) Test

Each shoulder test was assessed for:
1. Presence of pain (recorded on a Numeric Pain Rating Scale [NPRS], 0–10)
2. Provocation response (positive/negative)
3. Functional limitation, where applicable (e.g., HTS scored on a 5-point scale)
4. Range of motion (measured with a goniometer for abduction)

After baseline testing, an experienced MDT-certified clinician performed a standardized Mechanical Diagnosis and Therapy (MDT) assessment of the cervical-thoracic spine, which involved:
1. Repeated end-range movements (e.g., cervical retraction, extension, lateral movements)
2. Observation of mechanical and symptomatic responses (e.g., reduction of pain, improved ROM)
3. Identification of directional preference and potential centralization of symptoms

Based on MDT criteria, participants were classified into:
Cervical Derangement (CD): reducible condition showing symptom or mechanical improvement with specific movement
Cervical Non-Derangement (CND): no clear mechanical response observed

If a CD was confirmed, treatment was performed during the same session, using:
1. Continued repeated movements in the DP
2. Therapist-applied techniques if required (mobilizations)

After the intervention, the initial examiner (blinded to MDT findings) re-administered the five clinical shoulder tests to determine:
1. Whether previously positive tests became negative
2. Any improvement in NPRS pain scores
3. Functional improvement (≥20% or ≥1-point change on HTS scale)

The primary outcome was the change in shoulder test status (positive to negative) and/or symptom severity immediately after MDT intervention.

Intervention Type
Other

Primary outcome(s)
1. Change in clinical shoulder test results measured using five standardized physical tests:
1.1. Hand-to-Scapula (HTS) test
1.2. Neer test
1.3. Hawkins-Kennedy test
1.4. Jobe (Empty Can) test
1.5. Active shoulder abduction test
Each test is assessed for pain provocation and functional limitation at baseline (prior to intervention) and immediately post-intervention, both on Day One of the clinical assessment.
2. Pain intensity is measured using the Numeric Pain Rating Scale (NPRS; 0–10) during each shoulder test at baseline and immediately after MDT intervention, both on Day One
3. Shoulder range of motion is measured using a goniometer (specifically for active abduction) at baseline and immediately after intervention, both on Day One
4. Hand-to-Scapula (HTS) functional level is recorded using a 5-point ordinal scale at baseline and immediately post-intervention, both on Day One

A test was considered improved if:
1. Pain provocation decreased by ≥2 points on a Numeric Pain Rating Scale (NPRS; 0–10) during the test, or
2. Functional improvement was recorded:
2.1. ≥20% improvement in active range of motion (measured with a goniometer)
2.2. ≥1-point improvement on the HTS 5-point functional rating scale

Key secondary outcome(s))
1. Global perceived effect (GPE) on pain and function is self-reported by participants using a percentage improvement scale immediately post-intervention on Day One. A change of ≥20% is considered clinically meaningful.
2. MDT classification outcome is recorded by the treating therapist during the MDT assessment session on Day One. Based on the principles of Mechanical Diagnosis and Therapy (MDT), patients are classified as:
2.1. Cervical Derangement (CD)
2.2. Cervical Non-Derangement (CND)
Classification is guided by the presence or absence of a Directional Preference (DP) — a repeated movement direction that leads to symptom reduction, centralization, or improved function.

Questionnaires used in the study:
These were all completed at baseline (Day One) by the participant before the clinical shoulder and MDT assessments:
1. Neck-related disability (to screen out patients with significant cervical impairment) assessed using the Neck Disability Index (NDI)
2. Shoulder pain and functional impairment evaluated using the Shoulder Pain and Disability Index (SPADI) at baseline.
3. Shoulder function measured using the Simple Shoulder Test (SST) at baseline
4. General health-related quality of life measured using the RAND-36 Health Survey at baseline

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Primary complaint of shoulder pain
2. Pain localized to the shoulder region, specifically the deltoid area
3. Age 18 years or older
4. Ability to read and write Dutch
5. Ability to reproduce shoulder symptoms during clinical mechanical testing
6. Neck Disability Index (NDI) score ≤15/100. This threshold was used to exclude patients with significant neck-related disability.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
19 years

Upper age limit
57 years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Neck Disability Index (NDI) score >15/100
2. To exclude individuals with significant cervical spine involvement
3. Known or suspected specific shoulder or neck pathology, including:
3.1. Cervical spinal stenosis or nerve root compression
3.2. Shoulder or cervical fractures
3.3. Adhesive capsulitis (frozen shoulder)
3.4 History of cervical or shoulder surgery within the previous 6 months
3.5. Recent traumatic injury affecting the shoulder or cervical spine
3.6. Signs or symptoms of cervical radiculopathy
4. Serious comorbidities that could interfere with participation, such as:
4.1. Active cancer or metastases
4.2. AIDS or immunodeficiency
4.3. History of cerebrovascular accident (stroke)
4.4. Psychiatric or cognitive disorders that could impair understanding or compliance
5. Inability to demonstrate reproducible shoulder symptoms during baseline mechanical examination
6. Inability to provide informed consent or complete questionnaires in Dutch

Date of first enrolment
26/09/2016

Date of final enrolment
26/04/2017

Locations

Countries of recruitment
Belgium

Study participating centre
Kinepraktijk Vandeput
Dr. Haubenlaan 13

Maasmechelen
Belgium
3630

Study participating centre
Jeroen Vinck
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Sponsor information

Organisation
Universitair Ziekenhuis Leuven

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Will individual participant data (IPD) be available (including data dictionaries)?
Yes, upon reasonable request.

What data in particular will be shared?
An anonymized dataset including:
1. Participant demographics (age, gender)
2. Baseline and post-intervention results of clinical shoulder tests (Neer, Hawkins, Jobe, HTS, Abduction)
3. Numeric Pain Rating Scale (NPRS) scores
4. MDT classification (Cervical Derangement vs. Non-Derangement)
5. Global Perceived Effect (pain and function)

When will the data be available?
From 6 months after publication of the primary results, for a period of 3 years.

With whom will the data be shared?
Data will be made available to qualified researchers or clinicians with a legitimate academic or clinical research purpose.

For what types of analyses?
The data may be used for:
1. Pooled analyses or meta-analyses
2. Secondary analyses of MDT response profiles
3. Research into diagnostic differentiation in shoulder pain populations

How will the data be shared?
Interested researchers may contact the corresponding author (David Vandeput, david.vandeput@kuleuven.be). Access will be granted via a data-sharing agreement ensuring proper use and data protection.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	24/04/2025	No	Yes