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The effect of mechanical traction on cervical radiculopathy: protocol for the TracCerv2 single-blind, randomised controlled trial

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Abstract

Objectives To evaluate the effect at 3 months of an intensive cervical traction protocol on disability in people with cervical radiculopathy and compare with placebo traction.

Design The trial is national, multi-centre, randomised, placebo-controlled and single-blinded. It began in March 2024 and will end in September 2027. Participants are allocated to receive mechanical cervical traction or placebo mechanical cervical traction.

Setting Seven hospitals in France.

Participants We will include 206 individuals with cervical radiculopathy diagnosed 3 to 12 months previously, hospitalised to undergo mechanical traction. Main inclusion criteria: age ≥ 18 years, Neck Disability Index ≥ 15/50 points and presence of ≥ 3 of 4 diagnostic signs of cervical radiculopathy.

Interventions All participants undergo 2 × 30 min of traction per day for 5 consecutive days. For mechanical cervical traction, the maximum weight is ≤ 12 kg and for placebo traction ≤ 600g.

Main outcome measures The primary outcome is disability (Neck Disability Index), secondary outcomes include pain related outcomes, medication consumption, surgery and days off work.

Results This study will provide a robust evaluation of the mid-term effectiveness of mechanical traction on disability in chronic cervical radiculopathy. The results will demonstrate whether a simple technique involving a short, intensive protocol reduces the duration of disability and pain.

Conclusions The availability of robust evidence supporting or refuting the use of cervical traction as part of the management of cervical radiculopathy will enable optimisation of treatment. The results could lead to the drafting of evidence-based recommendations regarding the use of mechanical traction to treat cervical radiculopathy.

Clinial trial registration number ClinicalTrials.gov (NCT05952167).

Keywords Traction, Cervical radiculopathy, Disability, Pain

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Contribution of paper

- This study will provide a robust evaluation of the mid-term effectiveness of mechanical traction on disability in chronic cervical radiculopathy.
- The results will demonstrate whether a simple technique involving a short, intensive protocol reduces the duration of disability and pain.
- The results could lead to the drafting of evidence-based recommendations for or against the use of mechanical traction to treat cervical radiculopathy.

Introduction

Cervical radiculopathy is a prevalent condition caused by compression of the cervical spinal nerve roots [1, 2]. It causes neck and arm pain and disability, which can lead to time off work and high care costs [2]. The effectiveness of surgical intervention is limited and comports risks [2, 3]; therefore, the first intention treatment is conservative. The main treatment is physiotherapy, including manual therapy, exercise, mechanical traction and education [1–3].

Mechanical cervical traction involves stretching the cervical spine and soft tissues to open the intervertebral foramen and mobilise the facet joints [3]. Few studies have evaluated the effects of cervical traction. Therefore, recommendations published by the North American Spine Society [1] and a literature review [4] concluded that there was little effect on pain and disability. Danish recommendations for the treatment of cervical radiculopathy of recent onset (< 12 weeks) [5] include cervical traction; however, they state that the quality of the evidence supporting this is very low. Clinical practice guidelines recommend mechanical traction for the treatment of chronic neck pain but state that the level of evidence is only III [6]. However, a more recent systematic review of 5 studies [3] concluded that mechanical traction effectively reduced disability at the intermediate term and pain at the short and intermediate term; and that manual traction had a significant short-term effect on pain. Furthermore, there appeared to be a dose–effect relationship.

Most studies have compared manual therapy and exercise with manual therapy, exercise and cervical traction [3]. However, to fully conclude that traction is effective, it must be compared with placebo traction. Young et al. [7] compared manual therapy, exercise and cervical traction with manual therapy, exercise and placebo cervical traction (ineffective weight) and found no between-group difference at 2 and 4 weeks. The intensity of the traction protocol was relatively low (ie, 2 sessions per week over 4 weeks) in comparison with studies that suggest a beneficial effect of traction [3, 8], which could explain the lack of an effect.

A preliminary study evaluating a 5-day intensive cervical traction protocol showed an improvement in the Neck Disability Index (NDI) at 3 months that was greater than the minimum clinically important difference (MCID) in 17 of 36 participants [8]. Significant improvements were also found in the NDI and pain intensity at day 5 and 3 months [8]. The effect was larger than that found by Young et al. [7], suggesting that it was larger than the natural resolution of cervical radiculopathy. Studies with robust experimental designs are required to support or refute this treatment to optimise current practices.

The primary aim of this study is to evaluate the medium-term (3 months) effect of an intensive protocol (2×30 min of traction per day for 5 consecutive days) of mechanical cervical traction on disability in people with cervical radiculopathy, and to compare with the effect of placebo cervical traction.

The secondary aims are to compare the change in pain, an important criterion for affected individuals, signs of radiculopathy, which are indicative of the presence of the pathology that the treatment is designed to reduce, and medication consumption, need for surgery and days off work, which are important economic factors for the healthcare system and society.

Methods

Design and setting

The trial is national multi-centre, single-blinded, randomised, and placebo-controlled. Participants are hospital inpatients. The trial began in March 2024 and will end in September 2027. Seven centres in France are participating (CHU Rouen, APHP La Pitié Salpêtrière, CHU Nantes, CHU Limoges, CHU Emile Roux—Le Puy-en-Velay, CH La Rochelle, CHD Vendee). Participants are allocated to receive mechanical cervical traction or placebo mechanical cervical traction.

Ethical and regulatory aspects

Ethical approval was granted by: Comité de protection des personnes Sud-Méditerranée I, number -23.01774.000234. Verbal consent is collected from participants, in line with French regulations for category 2 interventional research.

People attending a consultation prior to hospitalisation for cervical traction are informed about the study by the physician and receive an information letter. Verbal consent is either collected immediately by the physician or on the 1st day of hospitalisation by a physiotherapist if the person wishes some time to make their decision.

The trial is registered at ClinicalTrials.gov (NCT05952167). The reporting follows the SPIRIT and TIDieR guidelines.

Allocation and blinding

Participants are randomly allocated to either the intervention (mechanical cervical traction) or placebo comparator (placebo mechanical cervical traction) group. Randomisation is performed by a physician or physiotherapist on D0, 1st day of hospitalisation after verification of the person's eligibility, using a central server (Ennov Clinical). Randomisation is stratified by centre with blocks of a 1:1 ratio.

Trial participants are blinded to their group allocation; however, assessors are not blinded.

Inclusion/exclusion criteria

The inclusion criteria are age ≥ 18 years; NDI ≥ 15/50 points; presence of at least 3 of the 4 diagnostic signs of cervical radiculopathy [9]: a) positive upper limb nerve tension test A (ULNT1a), b) < 60° cervical rotation towards the side concerned, c) positive cervical distraction test and d) positive Spurling test; cervical radiculopathy diagnosed 3 to 12 months previously; having not undergone cervical traction in the 5 years prior to inclusion; MRI or CT scan performed prior to hospitalisation to diagnose cervical radiculopathy; able to understand the protocol; having given verbal informed consent for participation; affiliated to the social security system or entitled beneficiary and hospitalisation planned during a week with no public holidays.

The exclusion criteria are known vertebral artery pathology at the time of inclusion; myelopathy, cervical cancer, cervical fracture, cervical dislocation, cervical spondylolisthesis or spinal infection; symptomatic cervical pain without radiculopathy; cervical surgery in the 2 years prior to inclusion; participation in another clinical research protocol with an impact on the objectives of the research; pregnancy or breast-feeding; and under guardianship or curatorship, or deprived of liberty; under an active protection mandate; under family habilitation services or under court protection.

Interventions and treatment schedule

Participants in both groups follow the same treatment schedule [8]. They are hospitalised for 5 days. On the first day of hospitalisation (D0), they undergo a medical examination as part of standard care, and their medication is modified if necessary. The physiotherapist also assesses them (see Outcome measures and Study timeline). From D0 to D4, they undergo two traction sessions per day according to group allocation.

Every day, before the afternoon traction intervention, participants also receive education from the physiotherapist about avoiding prolonged static positions [10], good spinal posture and remaining physically active [6].

Between the traction sessions, they are instructed to perform the following mobility and strength exercises [3, 7, 8]:

- Protraction/retraction, left/right rotation and flexion/extension movements as far as possible within the limits of pain or stiffness) regularly throughout the day.
- Self-resisted exercises in sitting with the hand providing resistance to isometric neck movements in all directions and standing against a wall for resisted retraction. Each exercise is held for 15 s and repeated 5 times.

On D1, 2 and 3, the physiotherapist performs a 15-min massage in the morning to relax the cervical and shoulder muscles (effleurage, kneading, muscle tension release, mobilisation of the cervical spine and stretching as required [6, 8].

Mechanical cervical traction (based on [8])

The traction is performed by a physiotherapist. To ensure standardisation, all participating physiotherapists participated in a 1h30 training session and received a protocol information document including photographs of the traction set-up.

The traction schedule is identical for both groups: 30 min, twice per day (sessions at least 2 h apart) for 5 consecutive weekdays (5 min progressive, 20 min at target weight, 5 min degressive).

Intervention group

- Intensity: Progressive from 5 to 10% of body weight over 5 days—Maximum: 12kg
- Angle: 45

Placebo group

- Intensity: Progressive from 0.10 to 0.6kg over the week, (100gr on D0, 100gr + 250gr on D1 and D2, 100gr + 250gr + 250gr on D3 and D4).

The maximum weight will be 600g, which is far below the 2.25 kg proposed as a placebo [7] but is noticeable to the participant.

- Angle: 45°

Outcomes

Outcomes are evaluated by a physiotherapist at 5 time points (see Study timeline and the Table 1). To ensure standardisation of procedures, outcome evaluation was included in the 1h30 training session for the traction protocol.

The Neck Disability Index (NDI) is a self-administered scale to measure neck pain and neck-related disability. It consists of 10 items, each scored from 0 to 5 [11] (high scores indicate significant activity limitation. It has been translated into French [12] and is commonly used in studies of cervical radiculopathy [3, 8]. The MCID is 7 points [11].

The Numerical Pain Rating Scale (NRS) is a self-rated scale to measure pain intensity that is sensitive to change [13, 14]. It is scored from 0 (no pain) to 10 (the maximum imaginable pain). It is used in this study to rate cervical and radicular pain at the time of the assessment, and pain during motor imagery.

For the motor imagery, the participant will be given the following instructions: 'I'm going to ask you to imagine yourself performing a movement. Sit upright and imagine yourself turning your head alternately from left to right 5 times without actually doing the movement'.

The Neuropathic Pain Symptom Inventory is a self-administered questionnaire, valid and reliable in French, used to assess the intensity and symptoms of neuropathic pain [15]. It consists of 12 questions (10 relating to symptoms and 2 to the frequency and duration of pain), each assessed on a numerical scale from 0 to 10. The symptom scores will be used in the analysis, grouped into 5 classes to determine the treatment effects on the different symptoms of neuropathic pain. The total score will also be analysed.

Clinical Prediction Rules (CPR) are used to determine the presence of radiculopathy. A positive CPR is determined by the presence of at least 3 of the following 4 clinical signs [9]:

a) upper limb nerve tension test A: positive,
b) amplitude of cervical rotation on the side concerned < 60°,
c) positive cervical distraction test: relief.
d) positive Spurling test: reproduction of symptoms.

The Pain catastrophizing scale is a self-administered questionnaire developed to quantify an individual's experience of pain [16] that is validated in French [17]. It consists of 13 items related from 0 (not at all) to 4 (all the time). A total score is obtained (ranging from 0 to 52), as well as three subscale scores assessing rumination, amplification and helplessness.

We will also collect the following information:

- The type and dose of current medication for cervical radiculopathy (level 1, 2 and 3 analgesics, anti-inflammatories, neuroleptics, anti-depressants),
- Surgery performed for cervical radiculopathy.
- The cumulative number of days off work.

Primary end point

The primary endpoint is the between-group difference in the proportion of participants with a decrease of ≥ 7 points (MCID) [11] in the NDI at M3.

Secondary end points

Between-group difference in:

1. the proportion of participants with a decrease of ≥ 7 points (MCID) in the NDI at M1 and M12.

(The NDI cannot be assessed at D4 as hospitalisation makes it difficult to answer certain items).

2. change in NRS score for neck pain at D4, M1, M3 and M12.
3. change in NRS score for radicular pain at D4, M1, M3 and M12.
4. change in NRS score for motor imagery at D4, M1, M3 and M12.
5. change in Neuropathic Pain Symptom Inventory at D4, M1, M3 and M12.
6. the proportion of participants with ≥ 3 positive CPR signs at D4 and M3 [9]:

    a) upper limb nerve tension test A (ULNT1a): positive,
    b) amplitude of cervical rotation on the side concerned: < 60°,
    c) positive cervical distraction test: relief
    d) positive Spurling test: reproduction of symptoms.

7. change in pain catastrophizing scale score at M1, M3 and M12

(The pain catastrophising scale score cannot be assessed at D4 as hospitalisation makes it difficult to answer certain items).

8. current medication consumption for cervical radiculopathy at D4, M1, M3 and M12.
9. surgery for cervical radiculopathy at M1, M3 and M12.

Study timeline

The study consists of 5 assessment time points and 5 days of cervical or placebo traction (Table 1).

D0: 1st day of hospitalisation: Consent will be collected if not collected previously. The baseline evaluation will be performed by a physiotherapist and a physician. Randomisation will be performed.
D0-D4: The traction protocol will be performed.
D4: Assessment by the physiotherapist 1 hour after the last traction (except NDI at D4).

Participants will be issued with a prescription for standardised outpatient physiotherapy on discharge.

M1: A member of the research team will telephone the participant to perform the assessment.
M3: The participant will attend the hospital for assessment by the physiotherapist.
M12: A member of the research team will telephone the participant to perform the final assessment.

Safety

The study is a category 2 interventional research involving human subjects; therefore, adverse events (serious or non-serious) do not have to be notified to the sponsor. Notification will be made within the framework of the vigilance system in place in the care setting for the study.

Sample size

Based on our preliminary study [8], we estimated a success rate (reduction in the Neck Disability Index by at least 7 points; MCID [11]) of 50% in the traction group. Assuming a success rate in the placebo group of 30% (based on our clinical experience because no data from similar studies are available), 93 patients per arm are required for an 80% power and 5% alpha risk. To guarantee the power, 10% more individuals will be randomised, giving a total of 206 participants to include.

Recruitment

Potentially eligible individuals are recruited among patients attending the participating centres for traction as a treatment for cervical radiculopathy. To ensure adequate recruitment and achievement of the target sample size, prior to beginning the study we asked participating centres to determine the number of participants they could realistically include.

Data management

The identities of all participants is kept confidential, and a coding system is used for anonymity.

All the information required for the protocol is entered into the participant's electronic case report form (eCRF), including the data necessary to confirm compliance with the protocol and all the data required for the statistical analyses. Missing data are coded. All data entered are checked for consistency.

Statistical analysis

Statistical analyses will be performed by the biostatistician of the CHD Vendée Clinical Research Unit. The analyses will be conducted using R software version 4.2.0 or a later version. All statistical tests will be carried out with an alpha risk of 5%.

Analyses will be performed according to the intention to treat (ITT) principle and a per-protocol sensitivity analysis of the primary endpoint will also be performed.

All demographic data and other baseline characteristics will be described overall and by group for the ITT population. The description will include numbers and percentages for qualitative variables and minima, maxima, means (SD) and median (Q1:Q3) for quantitative variables.

Missing data and their reasons will be described for each group.

Missing data will be treated as treatment failure. Surgery within the first 3 months of treatment will also be considered treatment failure.

The primary endpoint is treatment success based on a 7-point reduction in NDI score at M3 compared with baseline. The success rate will be compared between the 2 groups using a Cochran-Mantel–Haenszel test with the centre as a stratification criterion.

The success rate will also be evaluated at M1 and M12. The comparison between the 2 groups will be carried out using the same model as for the primary endpoint.

The NRS scores will be compared between groups using linear mixed models taking into account the treatment effect, the time-point (D4, M1, M3 and M12) and a fixed-effects treatment x time-point interaction. The centre and the participant will be considered as random effects.

The total Neuropathic Pain Symptom Inventory scale scores will be compared between groups using linear mixed models taking into account the treatment effect, the time point (D5 and M3) and a fixed-effects treatment x time-point interaction. The centre and participant will be considered as random effects.

The total Pain Catastrophing Scale score will be compared between groups using the same type of model.

The presence of CPR signs will be assessed at D5 and M3. The number and percentage of participants with a positive CPR will be calculated at each time point and compared between groups using a

Table 1 Study schedule

	Study Period								
	Enrolment	**Allocation**	**Post-allocation**						**Close-out**
TIMEPOINT	***Inclusion visit***	**D0**	***D1***	***D2***	***D3***	**D4**	***M1*** ***± 7 days***	***M3*** ***± 10 days***	***M12 ± 15 days***
ENROLMENT:									
Eligibility screen	X	X*							
Informed consent	X	X*							
Allocation		X							
INTERVENTIONS:									
Cervical traction / Placebo		←	—	—	—	→			
Massage (15 mins)			X (am)	X (am)	X (am)				
ASSESSMENTS:							X	X	X
Neck disability index		X					X	X	X
NRS cervical pain		X				X	X	X	X
NRS radicular pain		X				X	X	X	X
NRS motor imagery pain (bilateral cervical rotation)		X				X	X	X	X
Neuropathic Pain Symptom Inventory						X	X	X	X
CPR signs						X		X	
Pain catastrophizing scale							X	X	X
Medication consumption						X	X	X	X
Surgery							X	X	X
Days off work							X	X	X

D day, *M* month, *am* morning, *NRS* numerical pain rating scale, *CPR* clinical prediction rule

*If not performed previously, the eligibility screen and informed consent collection will be performed at admission

Cochran-Mantel–Haenszel test, with the centre as a stratification criterion.

The use of stage 1, 2 and 3 analgesics, anti-inflammatory drugs, neuroleptics and antidepressants will be described at each stage and compared between groups.

The cumulative number of sick-leave days for participants in active employment will be assessed. Then, using a linear model that takes into account the random effect of the centre, it will be compared between groups at M12.

Data monitoring

Data monitoring is organised by the CHD Vendée's Clinical Research Unit. A clinical research assistant visits each site and verifies the patient consent forms, data collection forms for the patients included, patients' medical and nursing records, and the investigator's file.

No interim analyses will be conducted.

The criteria for premature termination are essentially:

- Withdrawal of consent
- Death of a participant
- Deviations from the protocol preventing continuation in the study
- The occurrence of serious adverse events preventing the continuation in the study

In the event of a participant's withdrawal of consent, the data already collected will be analysed in accordance with the regulations, but no other examinations or visits specifically for the protocol will be carried out. A participant's premature withdrawal will in no way change their usual care.

Access to data

The database will be provided upon request to the clinical research unit manager of the CHD Vendée Scientific Committee.

Discussion

This study will provide a robust evaluation of the mid-term (3 month) effectiveness of mechanical traction on disability in chronic cervical radiculopathy. The secondary outcome measures will provide an extensive evaluation of pain and pain-related symptoms as well as outcomes that are relevant to the healthcare system and society. The results will demonstrate whether a simple technique involving a short, intensive protocol reduces the duration of disability and pain. The availability of robust evidence supporting or refuting the use of cervical traction as part of the management of cervical radiculopathy will enable the treatment of this condition to be optimised. The results could lead to the drafting of evidence-based recommendations regarding the use of mechanical traction to treat cervical radiculopathy.

The results will have important implications for the French healthcare system. In France, many centres provide mechanical traction for people with cervical radiculopathy. However, given the lack of robust evidence on cervical traction for radiculopathy, this practice is based on beliefs rather than evidence. Furthermore, French law requires mechanical traction to be performed in the presence of a physician (Article R4321-8 of the French Public Health Code, 2004); therefore, it must be performed in a hospital setting, which is very costly. The results could lead to a change in this practice.

The main limitation of this study is the lack of blinding of assessors. However, ensuring the blinding of the team (clinical rehabilitator AND clinical research team) is very complex in rehabilitation. Nevertheless, the choice of a self-questionnaire to measure the primary outcome should limit the impact of this.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12906-025-04801-5.

Supplementary Material 1. SPIRIT checklist.

Supplementary Material 2. TIDieR checklist.

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Authors' contributions

Conception or design of the work: GC and TR; acquisition, analysis, or interpretation of data: GC, LP, ES, CM and TR; drafted the work or substantively revised it: RT, GC, LP, and CM.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Ethical approval was granted by: Comité de protection des personnes Sud-Méditerranée I, number 23.01774.000234. Verbal consent is collected from participants, in line with French regulations for category 2 interventional research.

Competing interests

The authors declare no competing interests.

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