Systematic review

Please select one of the options below to edit your record. Either option will create a new version of the record - the existing version will remain unchanged.

A list of fields that can be edited in an update can be found here

1. * Review title.

Give the title of the review in English

Clinical efficacy of systemic corticosteroid in neck pain and low back pain with and without radiculopathy: a systematic review and meta-analysis of randomized controlled trials

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

Efficacité clinique de la corticothérapie systémique dans les rachialgies avec et sans radiculopathie; une revue systématique et méta-analyse des essais contrôlés randomisés

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

01/06/2022

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

30/06/2022

5. * Stage of review at time of this submission.

This field uses answers to initial screening questions. It cannot be edited until after registration.

Tick the boxes to show which review tasks have been started and which have been completed.

Update this field each time any amendments are made to a published record.

The review has not yet started: Yes

Review stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No

Review stage	Started	Completed
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

François WELFERT

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:
Dr WELFERT

7. * Named contact email.

Give the electronic email address of the named contact.

francois.welfert@gmail.com

8. Named contact address

PLEASE NOTE this information will be published in the PROSPERO record so please do not enter private information, i.e. personal home address

Give the full institutional/organisational postal address for the named contact.

263 rue Vendôme 69003 Lyon

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+33614806594

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Collège Universitaire de Médecine Générale, Université Lyon 1, France

Organisation web address:
https://lyon-est.univ-lyon1.fr/formation/des-medecine-generale/college-universitaire-de-medecine-generale-cumg

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.
NOTE: email and country now MUST be entered for each person, unless you are amending a published record.

Dr François WELFERT. Collège Universitaire de Médecine Générale, Université Lyon 1, France
Professor Rémy Boussageon. Collège Universitaire de Médecine Générale, Université Lyon1, France
Dr Clara Blanchard. Université de Poitiers
Dr Elodie Charuel. Université de Clermont Ferrand
Dr Thibault Menini. Université de Clermont Ferrand

Dr Hélène Vaillant Roussel. Université de Clermont Ferrand
Dr Nemat Jaafari. Centre Hospitalier de Poitiers

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

None

Grant number(s)
State the funder, grant or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

What is the clinical efficacy of systemic corticosteroid therapy in neck pain and low back pain with and without radiculopathy

16. * Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

A systematic review of the literature will be performed for relevant literature using the following electronic databases: MEDLINE, EMBASE, COCHRANE CENTRAL, ClinicalTrials.gov and the WHO clinical trials registry http://www.who.int /ictrp/en/.
There will be no restrictions on the language or date of publication, and translations will be attempted for non-English articles.

17. URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible.

Or provide a URL or link to the strategy. Do NOT provide links to your search **results**.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Adult subjects (> 18 years old) with isolated low back pain, lumbar radiculopathy, isolated neck pain, cervicobrachial neuralgia (CBN), and every etiology regardless of type without any indicated surgical treatment. We will also use synonyms

for this condition such as radiculopathy, radicular pain, radicular symptoms, nerve root compromise, nerve root compression, lumbosacral radicular syndrome, nerve root pain, and nerve root entrapment.

19. * Participants/population.

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

Adult subjects (> 18 years old) with isolated low back pain, lumbar radiculopathy, isolated neck pain, cervicobrachial neuralgia (CBN), and every etiology regardless of type without any indicated surgical treatment.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

Eligible randomised controlled trials (RCTs) witch have investigated the efficacy of orally-administered, intramusculary administered or intravenously administered corticosteroids treatment versus placebo or no treatment. Trials will still be eligible for inclusion if they have investigated corticosteroids add on treatment like paracetamol or NSAID, but we will not include the comparisons with active treatments (corticosteroids vs NSAID for example)s. The dose and frequency of the corticosteroid intake will not be restricted.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

The control will be placebo or no treatment. Note : studies will still be eligible for inclusion if both the intervention and comparator groups have received the same additional baseline care, as long as the treatment contrast remains as oral corticosteroids versus placebo or no treatment.

22. * Types of study to be included.

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

we will include randomised controlled trials published in peer-reviewed journals and clinical trial registries.
If the trial has not been published, but identified in a clinical trial registry, we will attempt to contact the authors for additional data.
There will be no restrictions on the language or date of publication, and translations will be attempted for non-English articles.

23. Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

1. Pain
2. Disability/function

Measures of effect
For continuous (quantitative) outcomes, we will calculate the mean difference (or SMD standardised mean differences if necessary because of the diversity of assessment scales) with 95% CIs.

As much as possible, we will pool the risk ratios reported in the studies as these are often hazard ratios or adjusted risk ratios. For dichotomous (binary or qualitative) outcomes, we will calculate Risk Ratios (RR) with 95% CIs from the number of events and participants in each treatment group. If events are very rare (0 or 1 in each group of the RCT), we will pool data using Peto's methods (because corrections for zero cell counts are not necessary) with reported pooled Peto odds

ratios and associated 95% CIs.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review

Other pain outcomes (e.g, back pain intensity), quality of life, adverse events and any serious adverse event (i.e., life-threatening or resulting in hospital admission, or reported as a serious adverse event by the study authors), the number and nature of those adverse/serious adverse events, and the number of withdrawals due to adverse events.

Measures of effect
For all outcomes, the number of events in each group will be extracted. As much as possible, we will pool the risk ratios reported in the studies as these are often hazard ratios or adjusted risk ratios. For dichotomous (binary or qualitative) outcomes, we will calculate Risk Ratios (RR) with 95% CIs from the number of events and participants in each treatment group. For continuous (quantitative) outcomes, we will calculate the mean difference (or SMD standardised mean differences if necessary because of the diversity of assessment scales) with 95% CIs. If events are very rare (0 or 1 in each group of the RCT), we will pool data using Peto’s methods (because corrections for zero cell counts are not necessary) with reported pooled Peto odds ratios and associated 95% CIs.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Two researchers, independent from each other, extract the study characteristics:
- study method,
- description of the studied population,
- intervention of the study,
- outcome measures,
- assessment method of the efficacy of systemic corticosteroid therapy,
- study results

Articles were excluded if the title and/or the abstract did not correspond to the study design. If there was a doubt, articles were read entirely before being excluded. If the case of disagreement between the two researchers, a third independent contributor was called.

The data will be grouped by time assessment in four groups : immediate (24 hours) short-term (> 24 hours and < 2 weeks), intermediate term (>2 weeks and <6 weeks), and long term (> 6 weeks)

For adverse events, the number of cases and the total sample size of each group will be extracted. The definition of adverse events will include, but will not be restricted to, the number of patients reporting any adverse event, the number of patients reporting any serious adverse event, the number and nature of other adverse events and the number of withdrawals due to adverse events.

Furthermore, we will extract information on the corticosteroid used, the dose regimen, the duration of treatment, the time to administration (from commencement of symptoms), and any concomitant therapy.

Authors will also be contacted via email, and asked to provide further information, when required.

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

“the revised Cochrane risk-of-bias tool for randomized trials”- ROB2 -, was applied for each study by both researchers. The assessment was made independently before results were put in common. For each area, the risk of bias was assessed as low, moderate or high. The overall risk of bias was assessed.

Risk associated to multiplicity of statistical tests and type I error : In case of multiple testing of the main outcome (for example in case of multiple outcomes or intermediary analyses), we will check for adjustement methods to control the risk of a type 1 error (examples : Bonferroni's correction or outcome that were planned in hierarchal analysis). If this risk is not anticipated in the protocol, the risk of false positivity is high and the result of the sudy will then be considered as exploratory, even if a statistical difference is found.

If the primary outcome is a composite criterion, we will consider statistically significant results of an individual outcome of this composite criterion as a primary outcome with a controlled risk of type 1 error after checking for the risk of multiple testing (for example if planned in hierarchical analysis) or after checking for consistency.

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This **must not be generic text** but should be **specific to your review** and describe how the proposed approach will be applied to your data.
If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

For all outcomes, the number of events in each group will be extracted. As much as possible, we will pool the risk ratios reported in the studies as these are often hazard ratios or adjusted risk ratios. For dichotomous (binary or qualitative) outcomes, we will calculate Risk Ratios (RR) with 95% CIs from the number of events and participants in each treatment group. For continuous (quantitative) outcomes, we will calculate the mean difference (or SMD standardised mean differences if necessary because of the diversity of assessment scales) with 95% CIs. If events are very rare (0 or 1 in each group of the RCT), we will pool data using Peto's methods (because corrections for zero cell counts are not necessary) with reported pooled Peto odds ratios and associated 95% CIs. We will use a random-effect model meta-analysis to assess the treatment-effect of a drug, using the software called Review Manager for data treatment.

Statistical heterogeneity across trials will be assessed with the I^2 statistic.. When possible, we will use the results from intention-to-treat (ITT) analyses from the RCTs included. Publication bias will be evaluated directly by analysing trial registries and when the number of trials is sufficient by Egger's Test.

Quality of Evidence assessed by two methods: GRADE and REB (Rebuild the Evidence Base)

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

We will perform sub-groups analyses on the risk of bias of the studies (low risk of bias versus not low risk of bias), the route of administration (oral versus IM versus IV), molecules (methylprednisolone, dexamethasone, prednisolone), pain assessment by grouping the low risk-of-bias RCTs in cervicobrachial neuralgia and lumbar radiculopathy.

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review

Cost effectiveness	No
Diagnostic	No
Epidemiologic	No
Individual patient data (IPD) meta-analysis	No
Intervention	No
Living systematic review	No

Meta-analysis	Yes
Methodology	No
Narrative synthesis	No
Network meta-analysis	No
Pre-clinical	No
Prevention	No
Prognostic	No
Prospective meta-analysis (PMA)	No
Review of reviews	No
Service delivery	No
Synthesis of qualitative studies	No
Systematic review	Yes
Other	No

Health area of the review

Alcohol/substance misuse/abuse	No
Blood and immune system	No
Cancer	No
Cardiovascular	No
Care of the elderly	No
Child health	No
Complementary therapies	No
COVID-19	No
Crime and justice	No
Dental	No
Digestive system	No
Ear, nose and throat	No
Education	No
Endocrine and metabolic disorders	No

Eye disorders	No
General interest	No
Genetics	No
Health inequalities/health equity	No
Infections and infestations	No
International development	No
Mental health and behavioural conditions	No
Musculoskeletal	Yes
Neurological	No
Nursing	No
Obstetrics and gynaecology	No
Oral health	No
Palliative care	No
Perioperative care	No
Physiotherapy	No
Pregnancy and childbirth	No
Public health (including social determinants of health)	No
Rehabilitation	No
Respiratory disorders	No
Service delivery	No
Skin disorders	No
Social care	No
Surgery	No
Tropical Medicine	No
Urological	No
Wounds, injuries and accidents	No
Violence and abuse	No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

France

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them.
If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

no

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

no

No I do not make this file publicly available until the review is complete

35. Dissemination plans.

Do you intend to publish the review on completion?

No

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

neck pain, low back pain, radiculopathy, corticosteroid, systemic corticosteroid

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published.
New registrations must be ongoing so this field is not editable for initial submission.

Review_Ongoing

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission).
List authors, title and journal details preferably in Vancouver format.