# Journal club checklist

This checklist provides an outline that you can use to guide your discussion of any article in your journal club. Further advise and tools to use when critically appraising papers can be found in the [EBVM Resources page.](https://knowledge.rcvs.org.uk/evidence-based-veterinary-medicine/ebvm-resources/tools-guidelines-and-checklists/)

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| **Title** | **Equine umbilical cord mesenchymal stem cells demonstrate safety and efficacy in the treatment of canine osteoarthritis: a randomized placebo-controlled trial** |
| **What are the aims or objectives of the study?**  A clearly stated aim or objective will make it easier for you to assess whether the research has been appropriately designed to meet these aims. | The stated objective of the study is to demonstrate the efficacy and safety of mesenchymal stem cells (MSCs) for xenogeneic use with intra-articular administration in dogs with osteoarthritis.  It is also noted at the end of the introduction that the assessment of the safety and efficacy was being undertaken for regulatory purposes (that is to provide evidence for the licensing authorities). |
| **Where was the research carried out?** | The research was carried out at 2 veterinary hospitals in Spain (Madrid and Barcelona). |
| **Did the study meet regulatory and ethical standards** | The paper states that the trial followed the Technical Requirements for Registration of Veterinary Medicinal Products for Good Clinical Practice (VICH guidelines), and that approval for this clinical trial (428/ECV) was obtained from the regulatory authority in Spain and satisfied national regulatory and animal welfare standards and requirements.  Informed consent was obtained from dog owners prior to the inclusion.  What additional requirements would have been required to carry out this research in the UK? See:  [RCVS. Advice & Guidance: 25. Routine veterinary practice and clinical veterinary research](https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/routine-veterinary-practice/)  [VMD. Guidance: Animal Test Certificates](https://www.gov.uk/guidance/animal-test-certificates) |
| **Are there any potential sources of bias?**  Who is paying for the study? Is there any reason to think that there may be any sources of bias in the study? | It is noted that 3 of the authors are employed by EquiCord SL which owns DogStem’s European Marketing Authorisation.  There is no specific mention of the funding of the study, however, if this was being carried out to meet regulatory requirements it is most likely that it was being funded by EquiCord.  How do you think these factors may affect the study and presentation of results? |
| **Is there a specific research question or hypothesis?** | Although not explicitly stated the hypothesis is that Equine umbilical cord mesenchymal stem cells (EUC-MSCs) are safe and effective in the treatment of canine osteoarthritis. |
| **Why do you want to review this paper?** |  |
| **What methods did the researchers use?** | The study is a multicentric, placebo controlled, double-blinded randomised controlled trial (RCT). |
| **Is this methodology appropriate to the objectives or question?** | A placebo controlled RCT is appropriate for assessing the efficacy of a treatment in comparison to a placebo (no treatment).  However, when looking at the safety of a medication it is important to consider the number of animals that are assessed and the timescale over which they are monitored, in order to assess how likely it is that adverse events will be picked up.  More detailed guidance on the different types of study can be found in the [EBVM Toolkit Section 3](https://knowledge.rcvs.org.uk/evidence-based-veterinary-medicine/ebvm-toolkit/) |
| **Is the study design described clearly enough to enable you to follow what was done?** |  |
| **Are number and type of patients included in this study clearly described?** |  |
| **Are these patients relevant to your practice, if not what differences need to be considered?** |  |
| **Were the methods of blinding and randomisation clearly described?** | The paper states that patients were block randomised and that both the owner and the researcher were blinded as to whether the animal received the treatment (Equine umbilical cord mesenchymal stem cells) or placebo, by a single intra-articular injection. |
| **Were the groups similar at the start of the trial?** | Important issues to compare include age, severity of the condition, weight and gender. |
| **What data were collected to assess outcomes?**  **At what time points were these data collected?** | Data were collected through Clinical Assessment (physical examination and blood tests); orthopaedic assessment; Gait analysis using a force plate and an owner questionnaire. |
| **Are the results of the study clearly described?** |  |
| **What counted as a treatment success for orthopaedic assessment, gait analysis and owner questionnaire?** | Do you think these are appropriate definitions of success? |
| **What was the primary efficacy outcome (endpoint) that was reported.**  **Is this the most appropriate outcome to measure?** | The primary endpoint chosen was gait analysis and the percentage of dogs that showed an improvement of ≥ 5% using a force platform to measure peak vertical force at 8 weeks after treatment.  This outcome was chosen as an objective measure, but it may not be the outcome that most owners are interested in. |
| **How was the safety of the product assessed during this study?** | Blood sample, for haematology and biochemistry, were taken prior to treatment and at the end of the study to detect any possible abnormalities.  Owners were asked to report any adverse events and complete a quality-of-life questionnaire. |
| **How many and what type of adverse events were reported?** |  |
| **Are all patients accounted for in the analysis?**  **What impact could this have on the results of the study?** | 40 dogs were included in each group at the start of the study, but not all dogs attended for each assessment (the authors give a number of reasons for this, including COVID restrictions). |
| **Owners were asked to complete a long term follow up questionnaire.**  **How accurate do you think these results will be?** |  |
| **What are the limitations of the study?** |  |
| **Do the findings support or alter your current knowledge?** |  |
| **Can the results be applied to your practice?**  **Do the findings provide sufficient evidence for us to consider changing your current practice?** | How does this treatment compare to your current treatments for dogs with osteoarthritis? |
| **Having read the paper are there any other sources of information you need to access before changing practice?** | Other information you may wish to look at includes further information about Stem cells and this product in particular.  Regulatory information for this product.  Treatment recommendations for osteoarthritis in the dog |

**References**

*Advice & Guidance: FAQs – Routine veterinary practice and clinical veterinary research*. [Royal College of Veterinary Surgeons] [online] Available from: [https://www.rcvs.org.uk/setting-standards/advice-and-guidance/faqs--routine-veterinary-practice-and-clinical-veterinary/](https://www.rcvs.org.uk/setting-standards/advice-and-guidance/faqs--routine-veterinary-practice-and-clinical-veterinary/%20) [Accessed 15 March 2024]

*Guidance: Animal Test Certificates - Guidance on Animal Test Certificates (ATCs) required to carry out the field trial of a veterinary medicine in animals (clinical trial) in the UK*. [Veterinary Medicines Directorate] [online] Available from: <https://www.gov.uk/guidance/animal-test-certificates> [Accessed 15 March 2024]