# **External Clinical Reviewer form**

## **Reviewer Instructions:**

Reviewers are requested to respect the confidentiality of any material sent to them, in accordance with the COPE and ICMJE recommendations linked to below. You should not reveal any details of the paper or its review, during or after the peer-review process, beyond those that are released by the journal. We therefore ask that you do not post your review, whether the manuscript is ultimately published or not, on any publicly accessible website.

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## **Recommendation:**

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## **Conflict of Interest:**

*Please clarify whether you have a financial or other conflict of interest with the authors.*

X No. I do not have a conflict of interest with the authors

Yes. I do have a conflict of interest with the authors

*If you have a conflict of interest with the authors, please supply further details below:*

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Please use the following scale:

1 = Fails by a large or moderate amount; 2 = Fails by a small amount; 3 = Succeeds by a small amount; 4 = Succeeds by a moderate amount; 5 = Succeeds by a large amount

If your response to a question is 'Don't know', please select N/A and put a brief comment in the Confidential Comments to Editor box.

*The hypothesis is clearly stated*

N/A X1 2 3 4 5

*The subject addressed in this article is worthy of investigation*

N/A 1 2 3 4 X5

*The most important previous studies are cited as far as I know*

N/A 1 X2 3 4 5

*The information presented is new (or a replication that deserved to be done)*

N/A X1 2 3 4 5

*The research design is suitable*

N/A X1 2 3 4 5

*The methods are described specifically enough to be evaluated*

N/A X1 2 3 4 5

*The discussion addresses sources of systematic and random error*

N/A X1 2 3 4 5

*The conclusions are supported by the data*

N/A X1 2 3 4 5

*The summary accurately reflects the content of the paper*

N/A X1 2 3 4 5

*Overall Score*

N/A X1 2 3 4 5

## **Reviewer Comments to Author:**

A detailed appraisal for the author, which should be divided into MAJOR comments and MINOR comments, with annotations given according to page and paragraph. This part is sent to the authors so please ensure that your comments are constructive and useful. Some reviewers may wish to put their name to these comments; if a name is added, this will be forwarded to the authors.

This article raises two main concerns:

1. Statistical methods. The study claims to have randomised patients to different wards (5 where vitamin D was given, versus 3 where it wasn’t). The abstract suggests that it was the patients who were randomised when in fact it was the wards. No description of which method ensured that the patient was assigned to a given ward.

Even if such randomisation procedure existed, evident space constraints during the first pandemic wave would have made impossible to randomly allocate patients.

If wards were randomised to each treatment, it is necessary to explain why it was 5 vs 3 and not 4 vs 4. Also, this allocation would need a cluster design analysis, which hasn’t been done.

In order to clarify this, I ask the authors to provide a reanalysis of this data with the help of an expert Epidemiologist or Statistician to address all sources of bias. I also ask them to make use of the reporting guidelines available in the EQUATOR Network.

2. Statistical issues in data collection.

The authors claim that data collection started in March the 1st and finished in May the 31st. However,, there was no approved, registered RCT in Spain for this study in those dates. This is easily searchable from the REEC (Spanish RCT registry) portal.

There's an ongoing trial led by a Cordoba hospital that matches the COVIDIOL study https://reec.aemps.es/reec/estudio/2020-001717-20. However, the dates of approval don't match the ones declared in the manuscript: First patient recruited in the COVIDIOL registered RCT: 5-06-2020.  
  
The authors declare collecting data much earlier, between March 1st & May 31st 2020. The study description by the authors resembles one made with observational data collected before a trial. If this is the case and we are reading an observational study, sources of bias need to be addressed by an expert statistician to enable interpretability of the study and its validity.

## **Reviewer Confidential Comments to Editor:**

A brief appraisal for the editor, which should give a frank account of the strengths and weaknesses of the article. This part is confidential. If you would like to consult one or more of your colleagues, please indicate their assistance in your comments to the editor.  
  
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I recommend a rejection and resubmission as a reanalysed study, but a better option would be to wait for the full COVIDIOL RCT results.  
  
I also ask this preprint to be taken down from the Lancet servers, recommending the authors to submit it to MedrXiv, to allow for continuous improvements and extensive prepublication review.