



MRC
Biostatistics
Unit



UNIVERSITY OF
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Publishing a Protocol: lived experience

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28th November 2023

STUDY PROTOCOL

Open Access

Effect of high-flow nasal therapy on patient-centred outcomes in patients at high risk of postoperative pulmonary complications after cardiac surgery: a study protocol for a multicentre adaptive randomised controlled trial



Melissa Earwaker^{1*}, Sofia Villar¹, Julia Fox-Rushby³, Melissa Duckworth¹, Sarah Dawson², Jo Steele¹, Yi-da Chiu⁴, Edward Litton⁵, Gudrun Kunst³, Gavin Murphy⁶, Guillermo Martinez⁶, Vasileios Zochios⁷, Val Brown¹, Geoff Brown¹ and Andrew Klein⁸

StratosPHERE 2: A response-adaptive randomised placebo-controlled Phase II trial to evaluate hydroxychloroquine and phenylbutyrate in pulmonary arterial hypertension caused by mutations in BMPR2

Nina Delu¹ [ORCID](#) [Email](#)

Rajenki Das¹

Angelique May²

Jo Steele³

Melissa Duckworth³

Rowena J Jones²

Martin R Wilkins⁴

Mark Toshner²

Sofia S Villar¹

Positioning imatinib for pulmonary arterial hypertension: A phase I/II design comprising dose finding and single-arm efficacy

Martin R. Wilkins¹, Mikel A. Mckie², Martin Law², Andreas A. Roussakis¹, Lars Harbaum¹, Colin Church^{3,4}, J Gerry Coghlan⁵, Robin Condcliffe^{6,7}, Luke S Howard⁸, David G Kieley^{6,7}, Jim Lordan⁹, Alexander Rothman^{6,7}, Jay Suntharalingam¹⁰, Mark Toshner^{11,12}, Stephen J Wort¹³ and Sofia S. Villar²

STUDY PROTOCOL

Open Access

Continuous Positive Airway Pressure plus Mandibular Advancement Therapy (PAPMAT): study protocol for an adaptive randomised crossover trial comparing the benefits and costs of combining two established treatments for obstructive sleep apnoea



Martin Law^{1*}, Sofia Villar¹, Nicholas Osoff², Victoria Stoneman³, Julia Fox-Rushby⁴, Yi-Da Chiu¹, Jo Steele⁵, Thomas Devine³, Claire Francis², Thomas Claydon³, Graham Hill⁶, Ka Keat Lim⁴, Joanna Rayner², Mandy Williams⁷, Emma Spire² and Timothy Quinnell²

Why publish the trial protocol?

- Increased validity;
- Helps other researchers:
 - Plan study with similar design;
 - Know that this study is taking place and its details (beyond clinicaltrials.gov);
- Increased impact;
- Publish or perish! Rare opportunity for applied statisticians to be the first author;
- May be the only published paper from the study.

How to publish the trial protocol

- Choose a journal (spoiler alert: it's *Trials*);
- Use the journal's template and share it.

Authorship

See <https://www.icmje.org>.

Same criteria as any other published manuscript:

- Substantial contributions to the conception/design of the work; or the acquisition/analysis/interpretation of data for the work; AND
- Drafting/critically reviewing the intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work.

Aside: The Statistical Analysis Plan

Publish this too! How? For *Trials* at least, in one of the following ways:

- Directly within the submitted protocol (if trial is simple);
- As an appendix alongside the submitted protocol;
- As an “addendum”/update to a published protocol;
- As a completely separate submission (inc. authors and DOI)

Practical lessons

- Your CTU's template may be very different to the journal's template, so consider updating your CTU's own templates to match the journal's.
- Start early:
 - If “converting” a protocol to the journal template, this becomes harder the more developed the protocol is.
 - If using the journal template as a guide only, there is still a great deal of work to be done.
- Expect it to take a long time, so...
- Get buy-in from co-authors!

Discussion

What is your experience of publishing trial protocols?