Reviewer's report

Title: A randomised controlled trial to determine whether intervals between blood donations can be safely and acceptably decreased to optimise blood supply: protocol of the INTERVAL trial

Version: 2 Date: 17 July 2014

Reviewer: Jacques Lacroix

Reviewer's report:

SUMMARY. – In this research protocol, Moore et al describe a large scale pragmatic randomized clinical trial (RCT) with two strata (male & female) and three arms. The study will be conducted in 5 static centres of the NHS Blood and Transplant in UK. It will enrol 50,000 participants. All consecutive donors will be asked to participate to the trial. If they agree, men will be allocated to “standard 12-week versus 10-week or versus 8-week interdonation intervals while women will be assigned to 16 vs 14 vs 12-week intervals. The primary outcome measure is the number of donation made over a 2-year period. This will compare, separately in men and women, using an intention-to-treat analysis. Secondary outcomes include quality of life of donors, anaemia, iron status, cognitive function, physical activity and donor attitudes. It is expected that the INTERVAL trial will show that shorter intervals increase significantly the number of donations without causing any safety issue.

MAJOR COMPULSARY REVISIONS

ABSTRACT

• The authors used the title “Methods/Design” rather that “Methodology”, which is the standard title for this section in the journal TRIALS.

BACKGROUND

• The authors wrote in their covering letter that they recruitment is expected to be completed by mid-June 2014, which is before this protocol will be published. Please, describe the status of the study at submission to TRIALS at the end of the BACKGROUND section.

METHODOLOGY

• The authors used the title “Methods/Design” rather that “Methodology”, which is the standard title for this section in the journal TRIALS.

• Intervention. – Men will be allocated to “standard 12-week versus 10-week or versus 8-week interdonation intervals while women will be assigned to 16 vs 14 vs 12-week intervals.

o It is unclear in my mind if this RCT is about the effect of advices to participants that they can donate in shorter intervals or is about the effect of shorter intervals?
If it is the latter question that is the primary question of the RCT, than how the investigators will deal with participants who deviate significantly from their allocated intervals should be better described in the manuscript.

How will be collected data on intervals between donations is not detailed in the manuscript.

ETHICS

• Proof of ethics approval: OK.

FUNDING

• Proof of funding: OK.

MINOR ESSENTIAL REVISIONS (not for publication).

References.

The references must be formatted according to the editorial standards of the journal TRIALS.

• The appropriate abbreviation should be used for the name of each journal (for example, Transfus Med Rev rather than Transfusion Medicine Reviews in reference 10).
• Delete all texts like “official journal of…” at the end of journal names.
• Reference 1. – “Lancet” rather than “The Lancet”.
• Reference 5. – Is this reference complete?
• Reference 6. – Is this reference complete?
• Reference 18. – Do not use capitalized words in the title.

Tables and captions.

• The legend of each table must include the definitions of all acronyms used (GP in table 3, HFE in Table 4, etc).

CONCLUSION.

The paper is very well written and it is easy to understand.

• The study is relevant: providing enough blood products is still a painful task that is very difficult to achieve for all blood banks across the world. The results of the randomized controlled trial (RCT) conducted by Dr Moore can increase blood collection very significantly. The last sentence of the manuscript is: “The study will generate scientific evidence to help formulate blood collection policies in England and elsewhere”. I agree.
• The hypothesis makes sense: shorter intervals between blood donation should increase blood collection.
• The research question is clear: does shorter interval between blood collection increase blood donation?
• The design of the study is great and the trial should bring out data that will answer the research question.

However, the points that I raise above must be addressed by the authors before this manuscript can be considered ready for publication by the journal TRIALS.

DISCRETIONARY REVISIONS.
• None.

REVIEWER
NAME: Jacques Lacroix, professor
Department of Pediatrics
Université de Montréal

MAILING ADDRESS:
Dr Jacques Lacroix
Pediatric Intensive Care Unit
Sainte-Justine Hospital, room 3431
3175 Côte Sainte-Catherine
Montréal (Québec)
Canada H3T 1C5
Telephone: (514) 345-4931 extension 5556
FAX: (514) 345-7731
E-mail: jacques_lacroix@ssss.gouv.qc.ca

Level of interest: An exceptional article

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.