SERVE TRIAL

Effect of phosphodiesterase-5 inhibition with Tadalafil on SystEmic Right VEntricular function – a multi-center, double-blind, randomized, placebo-controlled clinical trial

Publication strategy

Version 1 – August 1, 2016

The wish of the Steering Committee (Bouchardy J, Greutmann M, Tobler D, Schwerzmann M) is to make SERVE a project that

- has a high impact on clinical practice and research in Grown-Up Congenital Heart Disease (GUCH)
- allows to address different perspectives on patient outcomes in adults with a systemic right ventricle
- sets the signal for a good national collaboration among different specialists in the field of GUCH for the years to come

In order to optimize the potential of this project, a strategy for publications and authorship is provided in this document. Guidelines for authorship for the SERVE trial are based on published recommendations for authorship in multicenter studies.[1, 2] The present publication strategy follows the one used by Approach-IS Consortium.[3, 4]

1. Main papers

Two main papers are foreseen:
1. A methodological paper that serves as a reference for future publications, and will assure consistency in our methodological descriptions throughout articles to follow. This paper will be submitted to the Int J Cardiol or Am Heart J. All future SERVE publications should refer to this methodological paper. We anticipate that a draft will be circulated to co-authors by early 2017, once the final study protocol has been accepted by the regulatory authorities (Swiss Medics / KEK).

2. Study results**:** We will write an article that summarizes the study results with respect to the primary and secondary endpoints, as outlined in the study protocol. A draft of this paper will be circulated to co-authors in early-mid 2020.

Authorship on main papers:
1. Methodological paper (estimated number of co-authors: 15-16)
    . Shared first authors: Tobler D, Bouchardy J
    . Followed by: Research Fellow
    . Followed by: Project partners (Engel R, Heg D, Muller C; Frenk A)
    . Followed by: representatives core lab “MRI” (2 persons)
    . Followed by: representative core lab “CT” (1 person)
    . Followed by: representatives core lab “CPET” (2 persons)
    . Followed by: representative core lab “Neurohormones” (1 person)
    . Shared last authorship on byline: Greutmann M, Schwerzmann M

2. Study results (estimated number of co-authors: 23-25)
    . Shared first authors: Greutmann M, Tobler D
    . Followed by: Research Fellow (-s; up to 3)
    . Followed by: Project partners (Engel R, Heg D, Muller C, Frenk A)
    . Followed by: representatives core lab “MRI” (2 persons)
    . Followed by: representative core lab “CT” (1 person)
    . Followed by: representatives core lab “CPET” (2 persons)
    . Followed by: representative core lab “Neurohormones” (1 person)

. Followed by: 1 MRI specialist per participating center (centers performing > 20 MRI exams)
. Followed by: 1 ACHD cardiologist per participating center (centers including > 20 patients)
. Shared last authorship on byline: Bouchardy J, Schwerzmann M.

Furthermore, the entire SERVE Consortium will be acknowledged by including the statement "on behalf of the SERVE Consortium" at the end of the author list, and by referring to the Consortium as contributors at the end of the manuscript. See point 4 below for details.

2. Publications on collaborative sub-studies

Collaborative sub-studies are highly advocated. These sub-studies can be done using the entire dataset or with a sub-section of data. Numerous topics for collaborative sub-analyses can be proposed to the Steering Committee. For proposing sub-studies, please fill out the document at the end to this file and indicate the responsible applicant.

After review (to avoid duplication) and contacting Consortium members who proposed ideas, the topics will be assigned by the Steering Committee to the responsible applicants. However, if a collaborative sub-study has not been submitted for publication within 18 months of acceptance of the main papers, any sub-study may be available for re-assignment to other SERVE researchers. Responsible applicants of sub-studies have to confirm the acceptance of the publication strategy.

Sub-studies cannot be submitted for publication until both main papers have been accepted for publication. The Steering committee will take care that the main publications focus on the primary and secondary outcomes at outlined in the study protocol. Not published data can be reported in sub-studies.

Authorship on collaborative sub-studies:
For publications on collaborative sub-studies, the following authorship rules apply:

- The responsible author can invite up to 3 co-authors.
- One co-author from each participating center of which data have been used in the sub-analyses must be included.
- If not already included as co-author from a participating center, the Steering Committee and the research fellow(s) must also be included.
- If sub-studies refer to data from core labs, representatives from these labs must be included as co-authors as followed: MRI core lab (2 persons), CT core lab (1 person), CPET core lab (2 persons), neurohormones (2 persons)
- All authors should adhere to the International Committee of Medical Journal Editors (ICMJE) guidelines on authorship (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).
- The SERVE Consortium is acknowledged by including the statement "on behalf of the SERVE Consortium" at the end of the author list, and by referring to the Consortium as contributors at the end of the manuscript.
- The responsible author is free to select who will have the first, second, third or last position on the byline.
- The Steering Committee can decide if representatives from specific core labs not yet part of the author list should also be considered as co-authors.
- The order of authorship for the remaining co-authors depends on the contribution of each co-author to the project, i.e. coordinating/executive role and/or number of patients/data provided. The order in which authors are listed should be explained in a footnote to accurately describe the meaning of this order (Vancouver protocol: http://www.research.mq.edu.au/about/research_@_macquarie/policies,_procedures_and_conduct/documents/Vancouver.pdf).

Exceptions for authorship rules can be requested by email to the Steering Committee.

3. Additional conditions for authorship on all SERVE manuscripts

The following procedure should be followed to ensure timely review and manuscript submission to journals for peer review:

- Upon finalizing the manuscript, the main authors will send it to all co-authors for review and approval.
- Review and approval from an invited co-author must be given within four weeks.
- If the invited co-author does not respond within four weeks, it will be presumed that this individual declines authorship and his/her name will not be included on the manuscript.

4. SERVE Consortium

All publications should state the affiliation to the SERVE consortium (i.e., “on behalf of the SERVE Consortium”) and refer to the Consortium as contributors at the end of the manuscript.

All participating centers, partners, core labs and other contributors are invited to send a list of collaborators with a significant contribution to this study to the Steering Committee. The Steering Committee has to assure that the list of contributors is updated in a timely manner.

5. References

1. Barker A, Powell RA. Authorship. Guidelines exist on ownership of data and authorship in multicentre collaborations. Bmj 1997;**314**(7086):1046.
2. Bourbonniere MC, Russell DJ, Goldsmith CH. Authorship Issues: One Research Center's Experience With Developing Author Guidelines. American Journal of Occupational Therapy 2006;**60**(1):111-117.
3. Apers S, Kovacs AH, Luyckx K, Alday L, Berghammer M, Budts W, Callus E, Caruana M, Chidambarathanu S, Cook SC, Dellborg M, Enomoto J, Eriksen K, Fernandes SM, Jackson JL, Johansson B, Khairy P, Kutty S, Menahem S, Rempel G, Sluman MA, Soufi A, Thomet C, Veldtman G, Wang JK, White K, Moons P, consortium A-I, International Society for Adult Congenital Heart D. Assessment of Patterns of Patient-Reported Outcomes in Adults with Congenital Heart disease - International Study (APPROACH-IS): rationale, design, and methods. Int J Cardiol 2015;**179**:334-42.
4. Apers S, Kovacs AH, Luyckx K, Thomet C, Budts W, Enomoto J, Sluman MA, Wang JK, Jackson JL, Khairy P, Cook SC, Chidambarathanu S, Alday L, Eriksen K, Dellborg M, Berghammer M, Mattsson E, Mackie AS, Menahem S, Caruana M, Veldtman G, Soufi A, Romfh AW, White K, Callus E, Kutty S, Fieuws S, Moons P, consortium A-I, Isachd. Quality of Life of Adults With Congenital Heart Disease in 15 Countries: Evaluating Country-Specific Characteristics. J Am Coll Cardiol 2016;**67**(19):2237-45.

6. SERVE TRIAL SUB-STUDIES SUBMISSION FORM

YOUR NAME:

NAME OF YOUR CENTER:

PROPOSED RESEARCH QUESTION:

WORKING TITEL (Optional):

ADDITIOAL INFORMATION (Optional):

Will you or one of your colleagues conduct this sub-study and write an article on this:
O yes
O no

If yes, what will be the NAME OF THE PERSON RESPONSIBLE FOR THIS SUB-STUDY:

WHAT DATA COULD BE USED for this sub-study:
O My center's own data only
O Data from different centers

WHAT KIND OF DATA SHOULD BE USED TO ANSWER THIS RESEARCH QUESTION
O Data from University Hospital Basel
O Data from University Hospital Bern
O Data from University Hospital Geneva
O Data from University Hospital Lausanne
O Data from Kantonsspital St. Gallen
O Data from University Hospital Zurich

O Data from the core lab MRI
O Data from the core lab CT
O Data from the core lab Neurohormones
O Data from the core lab CPET

WHEN DO YOU PLAN TO ANALYZE THE DATA FOR THIS QUESTION