



Place in Site Master File #8

Quality criteria to be fulfilled by articles/manuscripts of preplanned and post-hoc sub-studies or analyses describing populations of patients randomized in the AID-ICU trial.

The sub-study administrative group consists of members of the AID-ICU trial Steering committee

There are three types of sub analyses/studies in the AID-ICU trial:

1. Analyses/studies using site-specific data
2. Analyses/studies using country-specific data
3. Analyses/studies using the complete AID-ICU database

Type 1 analyses/studies may be commenced and executed on the discretion of the site investigator/s and should fulfil criteria 1-4 outlined below.

When patients randomised in the AID-ICU trial are reported as a part of a larger sample from the site or reported to a registry the quality criteria below are not relevant.

Type 2 and 3 analyses/studies should be coordinated by the national investigator in each country participating in the AID-ICU trial and must fulfil criteria 1-4 below, and conducted according to the procedure described.

Criteria:

1. All manuscripts or abstracts describing patients randomised in the AID-ICU trial shall cite the main publication and describe the main results of the AID-ICU trial, as well as results on any secondary outcomes relevant for the sub analysis/study.
2. In a manuscript describing results of sub analyses of patients from the AID-ICU trial the methodology of the AID-ICU trial relevant for the sub analyses (randomised blinded placebo-controlled trial, stratification for site and delirium motor subtype etc.) shall be presented, including a citation of the design article. The methodology specific for the sub study or analysis shall be clearly



stated in the manuscript. Abstracts may limit this to a citation of the design article for the AID-ICU trial.

3. It shall be clearly stated in the protocol and the subsequent article if the analyses in the study have been pre-planned or arrived from hypotheses put forward after disclosure of the database of the results from the AID-ICU trial. This will distinguish *post hoc* studies describing subpopulations in the AID-ICU trial from pre-planned sub studies, previously recognised and approved by the Steering Committee.
4. The funding bodies should be acknowledged in all manuscripts involving the AID-ICU database.

Procedure:

1. All sub study project plans involving the AID-ICU database should initially be presented to the Steering Committee using a common template (see additional file 'substudy proposal form'). The Steering Committee will comment on the project described in the template within 14 days. Hereafter a full protocol should be developed and submitted to the Steering Committee. Final approval will be decided in the Steering Committee, at the latest 30 days after submission/resubmission of the full protocol.
2. When more than one protocol/hypothesis/idea on a similar research question arises, the groups responsible must collaborate.
3. After approval of the study protocol the study group will have 6 months from receiving the data set/receiving approval (whichever comes last) to complete the analysis and manuscript. The final manuscript shall undergo review from the Steering Committee within 30 days. The Steering Committee must accept the conclusions drawn before submission for publication (preferably by consensus but if this is unobtainable majority decision will apply).
4. Invitation to the author group should follow the Vancouver principles (please see next page) The AID-ICU Steering Committee should be invited, but to gain authorship they must contribute significantly in the development of the paper (according to the Vancouver principles). The paper should always include as last common author: "AID-ICU trial co-authors". All AID-ICU investigators must be acknowledged with name under "Contributors" in PubMed and in appendices to the manuscript if this option is available from the journal.



Vancouver Principles

The Vancouver Protocol is internationally recognised as the standard for determining authorship on publications and is now applied across all disciplines in the world's top universities (<http://icmje.org>). The principles are simple and states that to be credited as an author each and every author on a publication must have contributed in the following way:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work

AND

- Drafting the work or revising it critically for important intellectual content

AND

- Final approval of the version to be published

AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.