Author's response to reviews

Title: Design and rationale for the 6S - Scandinavian Starch for Severe Sepsis/Septic Shock trial - A double-blinded, randomised clinical trial comparing the effect of hydroxyethyl starch 130/0.4 with balanced crystalloid solution on mortality and kidney failure in patients with severe sepsis

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To the editors of *Trials*

We are grateful for the opportunity to further improve and resubmit our paper, and hope that you will find the re-revised manuscript suitable for publication in *Trials*.

The re-revised manuscript, which has been changed according to the issues raised by the reviewer, has been uploaded to the website as requested.

Our response to the comments from the reviewer is given below.

On behalf of the authors

Sincerely yours

Anders Perner, MD, PhD.

Response to prof. Goldsmith:
Thank you for the additional comments.

1. Done

2. As procedures differ between countries we have given details on how consent is handled in all countries: P5, 1st para and P11, para 7, L6-7: ‘(In Denmark: Two physicians followed by delayed consent from next of kin and the patient’s general practitioner. In Iceland, Finland and Norway: Next of kin)’.

3. You are absolutely right, and we have clarified data management after withdrawal in the re-revised manuscript: P8, para 4, L 3-8: ‘The person making the withdrawal will be asked for permission to obtain data for the primary outcome measure. If this person declines, no more data will be collected (except in Denmark and Finland where data for the primary outcome measure will be collected centrally). All randomised patients will be reported, and all data available with consent will be used in the analyses. If appropriate, multiple imputation will be used [24]. If there are patients with missing data for the primary outcome measure, new patients will be randomised to obtain the full sample size.’