

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	AnAnkle Trial study protocol: a randomised trial comparing pain profiles after peripheral nerve block or spinal anaesthesia for ankle fracture surgery
AUTHORS	Sort, Rune; Brorson, Stig; Gögenür, Ismail; Møller, Ann

VERSION 1 - REVIEW

REVIEWER	Mehmet AKSOY Department of Anesthesiology and Reanimation, Faculty of Medicine, Atatürk University, Erzurum, Turkey
REVIEW RETURNED	21-Jan-2017

GENERAL COMMENTS	In this study, authors presented a study protocol of an ongoing randomised study comparing primary peripheral nerve block anaesthesia with spinal anaesthesia for ankle fracture surgery regarding postoperative pain profiles and quality of recovery. This study protocol was reviewed in detail and carefully. This study protocol is scientifically credible and presented in an appropriate context; the design is ethically and procedurally sound.
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REVIEWER	Francesca L. Beaudoin, MD, MS The Alpert Medical School of Brown University Rhode Island Hospital and The Miriam Hospital Providence, Rhode Island, United States
REVIEW RETURNED	08-Feb-2017

GENERAL COMMENTS	The authors do a nice job providing justification for their investigation and detailing their clinical trial in such a way that it could be easily reproduced. A few minor comments: Any planned interim analysis should be mentioned (if none is planned, then this should also be stated) Is there any independent medical monitor or data safety monitoring board that can review AEs and if needed stop the trial based on adverse events? If so, please detail. There appear to be some newer studies that could be referenced (in foot/ankle surgery, fractures).
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REVIEWER	Kerem Erkalp University of Health Sciences Istanbul Bagcilar Training and Research Hospital Department of Anesthesiology and Reanimation
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REVIEW RETURNED	09-Mar-2017
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GENERAL COMMENTS	<p>BMJ OPEN-2017-016001; "An Ankle Trial study protocol: a randomised trial comparing pain profiles after peripheral nerve block or spinal anaesthesia for ankle fracture surgery"</p> <p>Dear Authors:</p> <p>Thank you for submitting your manuscript "An Ankle Trial study protocol: a randomised trial comparing pain profiles after peripheral nerve block or spinal anaesthesia for ankle fracture surgery" to BMJ OPEN for consideration.</p> <p>Your paper has an interesting and current topic. And it is suitable for the publication.</p> <p>Thank you again for submitting your manuscript to TARDD.</p>
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VERSION 1 – AUTHOR RESPONSE

We thank you for your time and your relevant comments regarding our paper. Below is our response to the points raised in the peer review.

Reviewer # 2:

"Any planned interim analysis should be mentioned (if none is planned, then this should also be stated)"

- No interim analysis is planned. This has been added in the "Sample size estimation" section on page 5 of the manuscript.

"Is there any independent medical monitor or data safety monitoring board that can review AEs and if needed stop the trial based on adverse events? If so, please detail."

- Yes, the independent GCP Unit monitors the handling and proper reporting of AE's to the authorities. The Danish Medicines Agency review reported AE's and will stop the trial if needed for safety reasons. This has now been clarified in the "Safety" paragraph on page 8.

"There appear to be some newer studies that could be referenced (in foot/ankle surgery, fractures)."

- Yes, but to our knowledge none with significant relevance to this trial were published at the time of trial initiation. Newer studies will be referenced and discussed in the later paper reporting the results of this trial.