

UPDATE

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# Update to the study protocol: minimisation of dialysis risk in hospital patients with chronic kidney disease (MinDial): a multicentre, stepped-wedge, cluster-randomised controlled trial

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## Abstract

This document reports a brief update to the previously published protocol of the MinDial study.

**Trial registration** German Clinical Trials Register DRKS00029691. Registered on 12 Sept. 2022, <https://drks.de/search/en/trial/DRKS00029691>.

**Keywords** Chronic kidney disease (CKD), Kidney failure risk equation (KFRE), End-stage renal disease (ESRD), Estimated glomerular filtration rate (eGFR), Stepped-wedge design, Cluster-randomised trial (CRT)

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## Update to the study protocol

The protocol of the MinDial study was previously published in *Trials* [1]. As stated in the subsection “Baseline data” of section “Participant timeline {13}”, the MinDial trial proceeds as follows:

*“To document serum creatinine, KFRE score, blood pressure and HbA1c in the eCRF, all values are taken at a time interval around the date when the KFRE score is  $\geq 15\%$  (date of laboratory determination before 20 June 2023) or  $\geq 9\%$  (since 20 June 2023) for the first time in the current case.”*

In June 2024, the study protocol was amended to be more specific on which of the measurements of the kidney failure risk equation (KFRE) score, serum creatinine and estimated glomerular filtration rate (eGFR) should be documented in the electronic case report form (eCRF), and to pre-specify the measurement designated as baseline. Accordingly, we would like to add the following as a supplement to the above paragraph:



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*“To be more specific, the KFRE score, serum creatinine and eGFR are documented at several time points:*

- KFRE score:
  - measurement on the day of the current hospital stay on a peripheral ward on which the KFRE score is  $\geq 15\%$  or  $\geq 9\%$ , respectively, for the first time;
  - measurement closest to the inclusion date (baseline);
  - measurement closest to discharge;
- Serum creatinine: measurements on the same days as with the KFRE score;
- eGFR: measurements on the same days as with the KFRE score.

*The measurements closest to the inclusion date are considered as the baseline and used for the evaluation.”*

Apart from this, the study protocol remains unchanged.

#### Abbreviations

eCRF	Electronic case report form
eGFR	Estimated glomerular filtration rate
KFRE	Kidney failure risk equation

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#### Authors' contributions

DS prepared this update document. All authors read and approved the final version.

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#### Availability of data and materials

Not applicable.

#### Declarations

##### Ethics approval and consent to participate

Ethics approval was granted on 27 June 2022 by the “Ethik Kommission der Ärztekammer Westfalen-Lippe und der Westfaelischen Wilhelms-Universitaet”, located in Muenster/Westfalen (2022–257-f-s). Furthermore, four amendments were made by the study team and approved by the ethics commission. Data protection documents were prepared by a legal adviser at Knappschaftskliniken and the responsible data protection commissioner of each participating clinic agreed to the data protection documents. Written, informed consent to participate will be obtained from all participants.

##### Consent for publication

Not applicable.

##### Competing interests

The authors declare that they do not have competing interests.

#### Reference

1. Stelzer D, Binder H, Glattacker M, et al. Minimisation of dialysis risk in hospital patients with chronic kidney disease (MinDial): study protocol for a multicentre, stepped-wedge, cluster-randomised controlled trial. *Trials*. 2024;25:368. <https://doi.org/10.1186/s13063-024-08182-x>.

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