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GLASGOW & VIRTUAL
JUNE 3-6, 2026
Challenge Your Thinking

FINEARTS-HF
FINerenone trial to investigate Efficacy and sAfety superioR to placebo in paTientS with Heart Failure

Dose-exposure-response analysis of finerenone on serum potassium and cardiovascular outcomes among patients with heart failure: Insights from FINEARTS-HF

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Background

- Finerenone reduces the risk of total heart failure events and cardiovascular death among patients with HF with mildly reduced or preserved ejection fraction

- Finerenone is also known to reduce NT-proBNP and raise serum potassium, compared with placebo

- Whether the effects of finereone are dose/exposure dependent is not clear

FINEARTS-HF Study design

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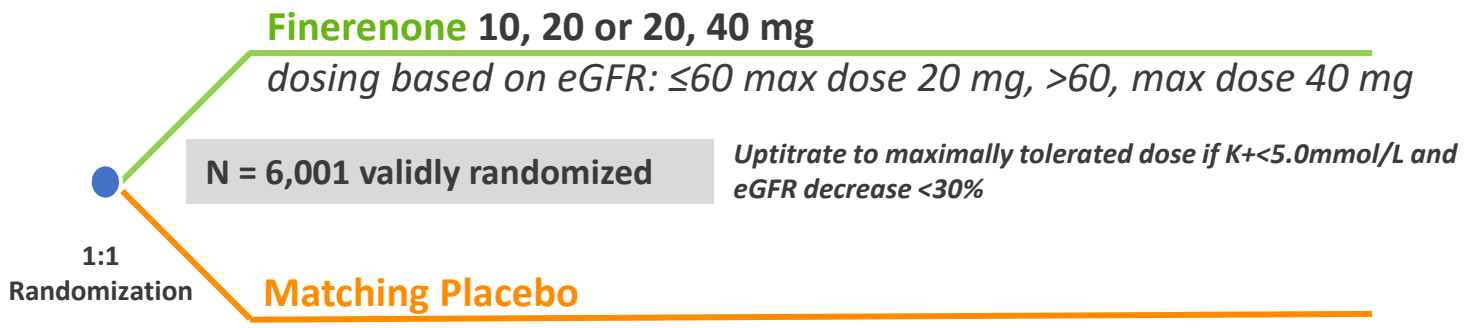
Randomized, double-blind, placebo-controlled trial of patients with HFmrEF/HFpEF

Key Inclusion Criteria

- **Symptomatic HF with LVEF ≥ 40%**
- **Age ≥40 yrs**
- **Elevated natriuretic peptide levels**
- **Structural heart disease (LA↑ or LVH)**
- **Diuretics in the 30d prior to randomization**

Key Exclusion Criteria

- **eGFR <25 mL/min/1.73 m²**
- **Potassium >5.0 mmol/L**
- **Symptomatic hypotension**
- **MRA use 30d prior to randomization**



Visits: Month 1, then 3-monthly for first 12 months, 4-monthly visits thereafter

FINEARTS-HF Dosing Algorithm – serum K

Serum / plasma potassium (K^+ mmol/L)		Action to be taken
First sample:		
<5.0		Increase to the next higher dose level (or continue at maximum permitted dose level)
≥5.0 to <5.5		Continue the current dose level
≥5.5 to <6.0		Down-titrate to the next lower dose if possible; if patient is already on dose level 1, interrupt study intervention. K^+ should be re-checked within 72 h of initial K^+ result awareness; follow **option a**
≥6.0		Interrupt study intervention and K^+ should be re-checked within 72 h of initial K^+ result awareness; follow **option b**
Second and subsequent sample:		
Option a	**<5.5**	Continue current dose
	≥5.5	Down-titrate to the next lower dose if possible, or interrupt study intervention and recheck K+
Option b	**<5.5**	Restart at dose level 1
	≥5.5	Continue to withhold study intervention, further monitoring of K^+. Restart at dose level 1 **ONLY** if K^+ is <5.0 mmol/L

Analytic Approach

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- For data visualization, finerenone dose was considered as the dose administered before the respective PD measurement
- Non-linear mixed effects models were fit to explore relationships of repeated measures of dose/exposure with outcomes

- Serum potassium
  - Thresholds of >5.5 and >6.0 mmol/L
- NT-proBNP
  - Ratio of current concentration to baseline
- Clinical Events
  - Repeated time to event analyses (CV death & total HF events)

Results

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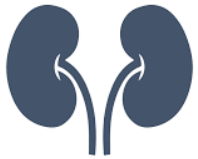
N=6,001



Mean eGFR 62 ±20
mL/min/1.73 m^2

n=3,168 eGFR >60
Finerenone 20 -> 40 mg/day

n=2,833 eGFR ≤60
Finerenone 10 -> 20 mg/day

Mean prescribed dose
33 ±9 mg/day

Mean prescribed dose
16 ±4 mg/day

Finerenone concentrations
n=6,658 measurements

Serum K+
n=123,720 measurements

Serum NT-proBNP
n=16,971 measurements

CV death & total HF
n=2,366 events

Pharmacokinetics of finerenone

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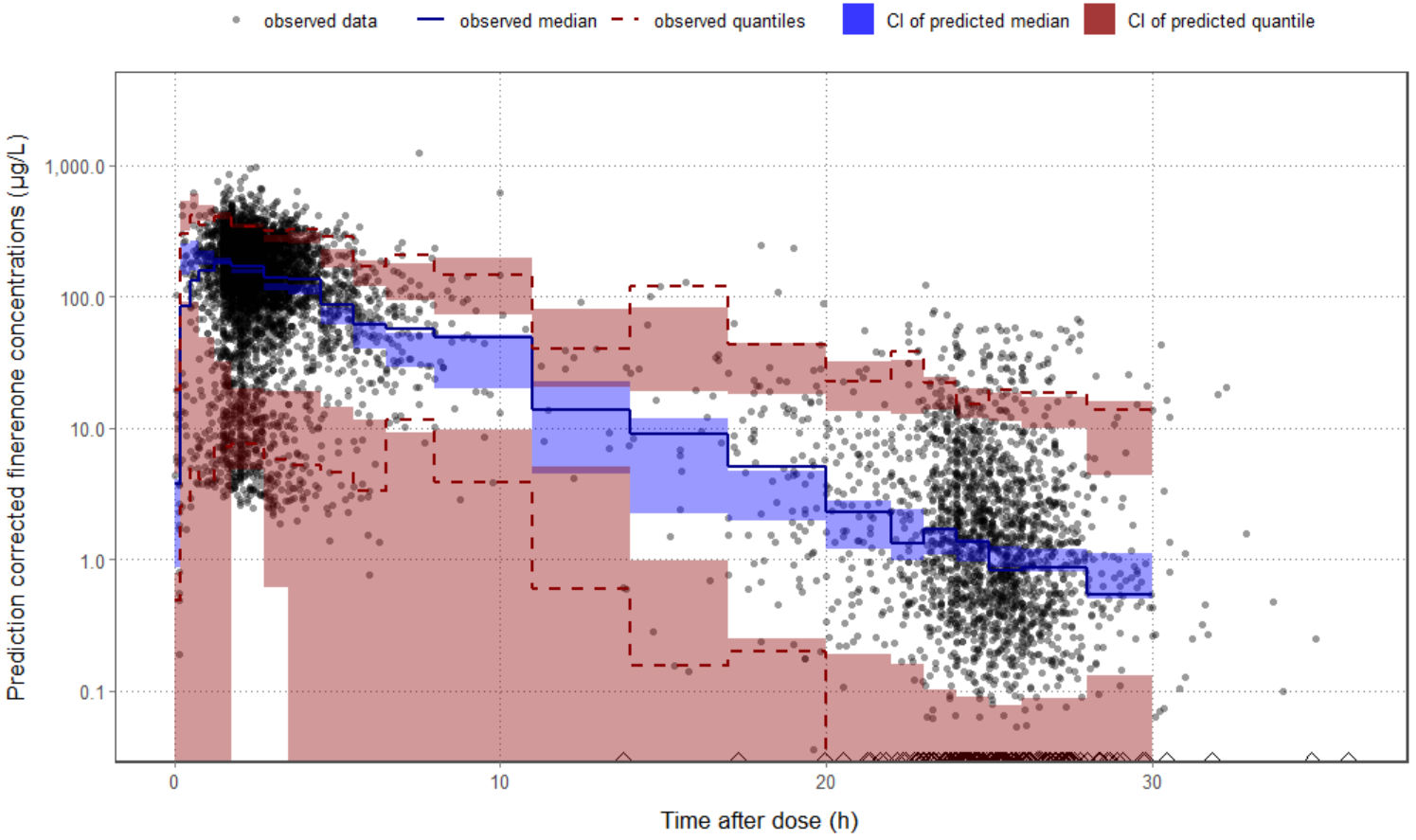

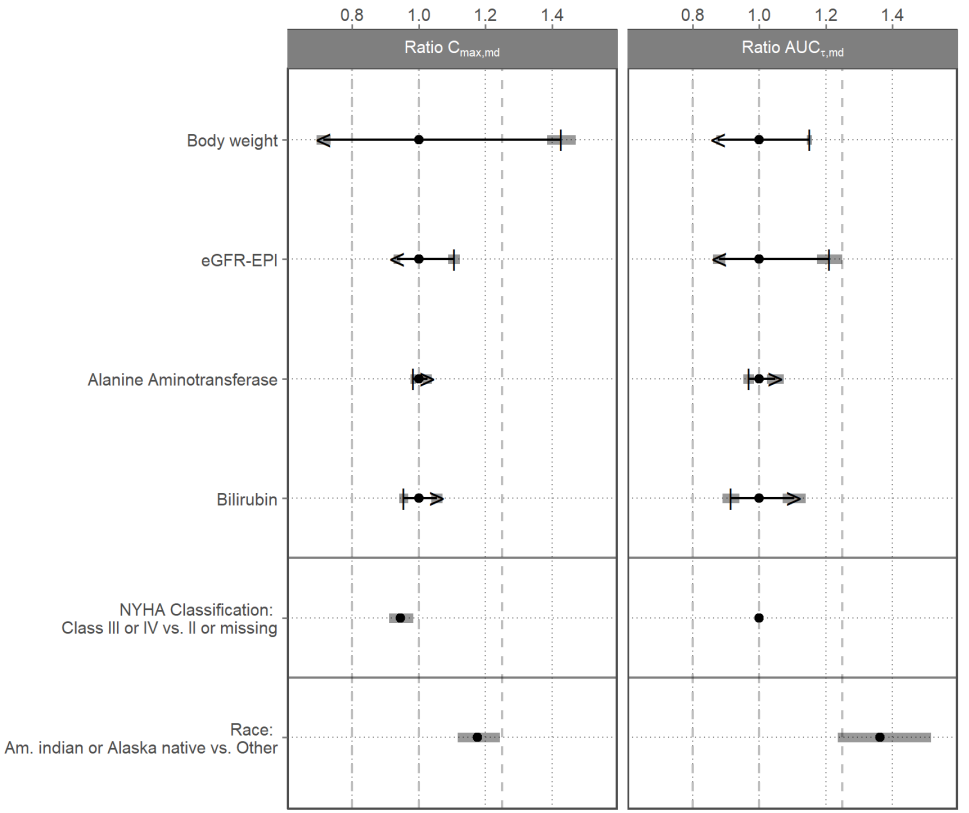

Finerenone dose and serum K

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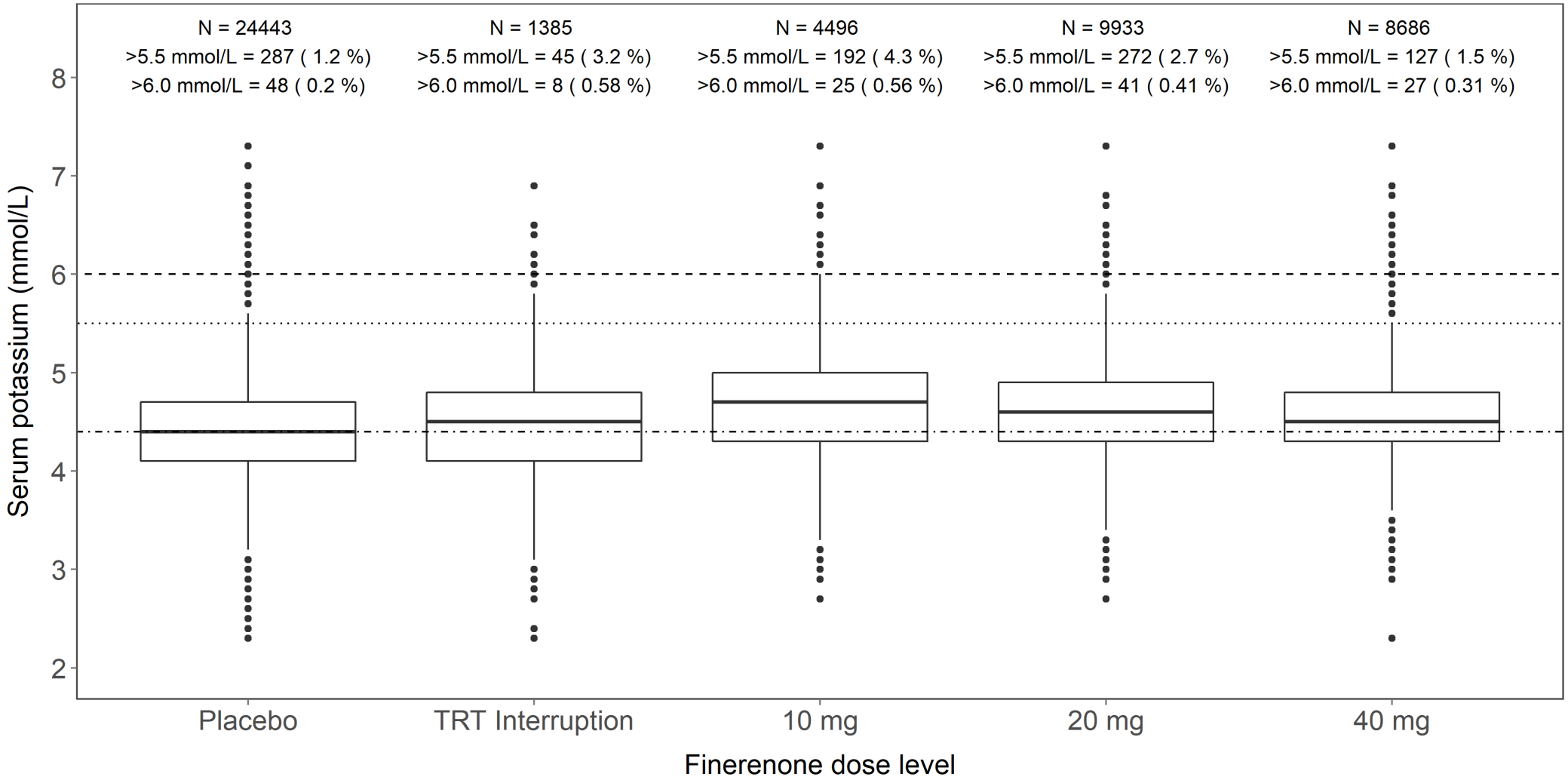

Post-baseline central lab data

Simulation studies – dose and serum K

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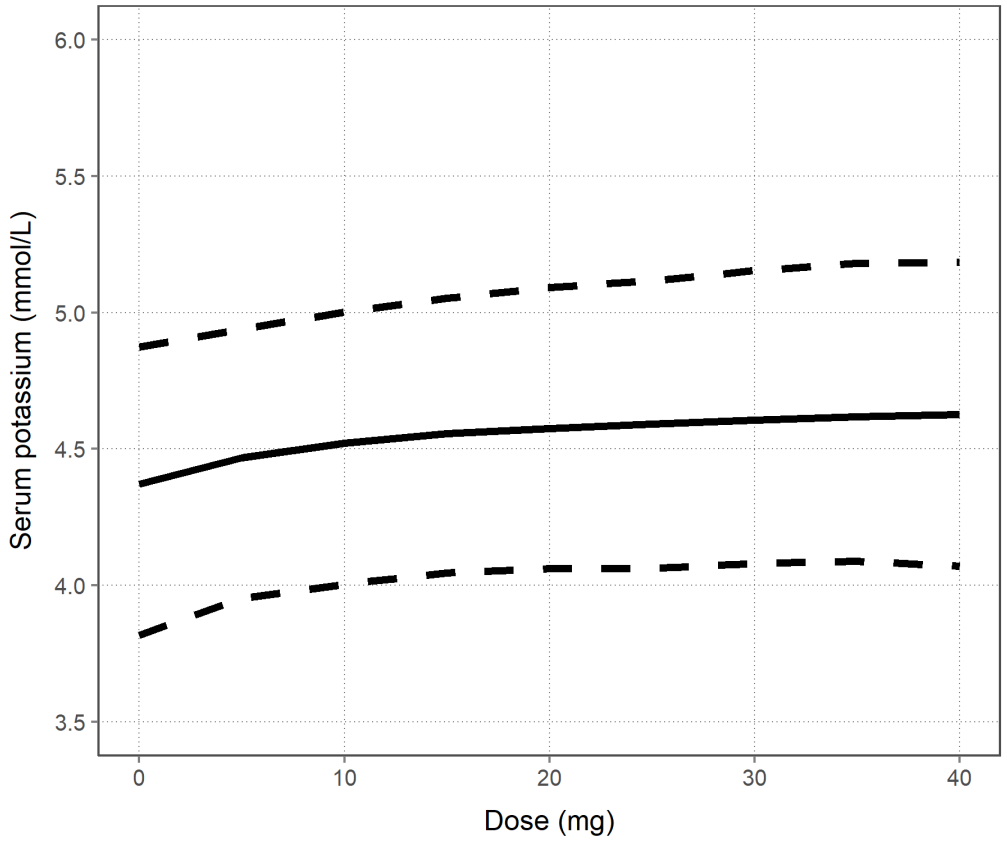
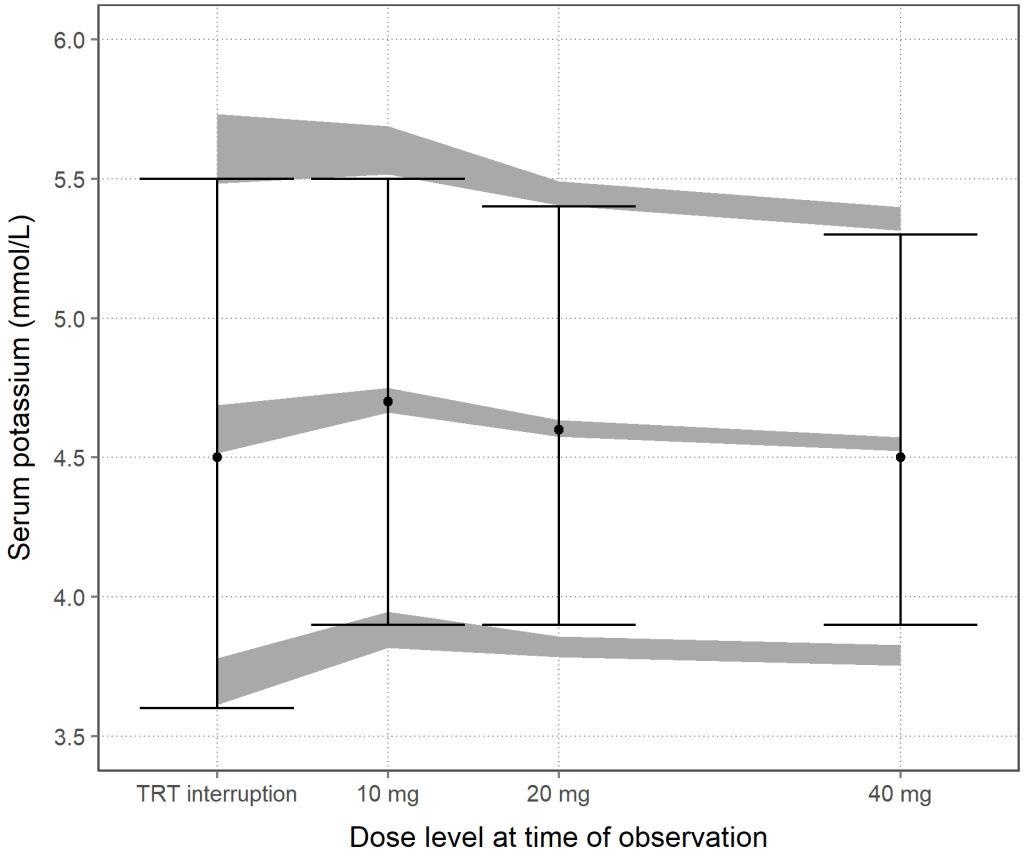
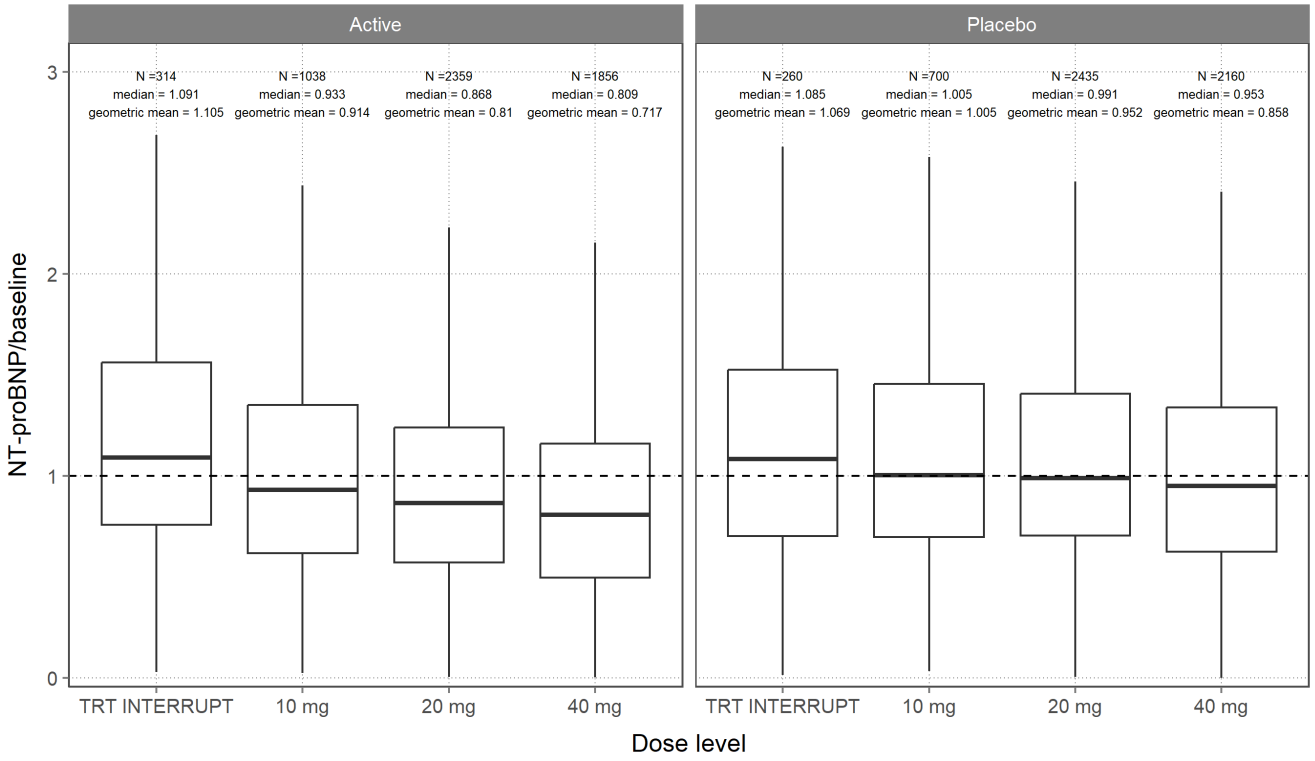
Without dose titration

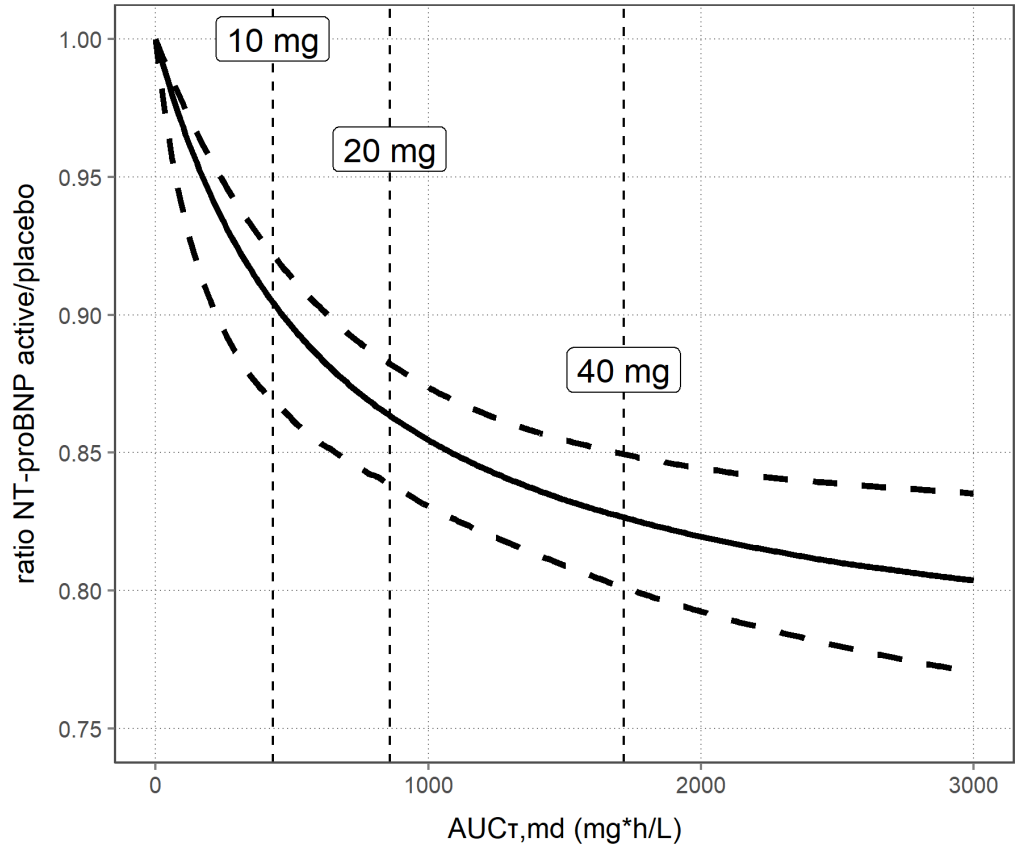


With dose titration

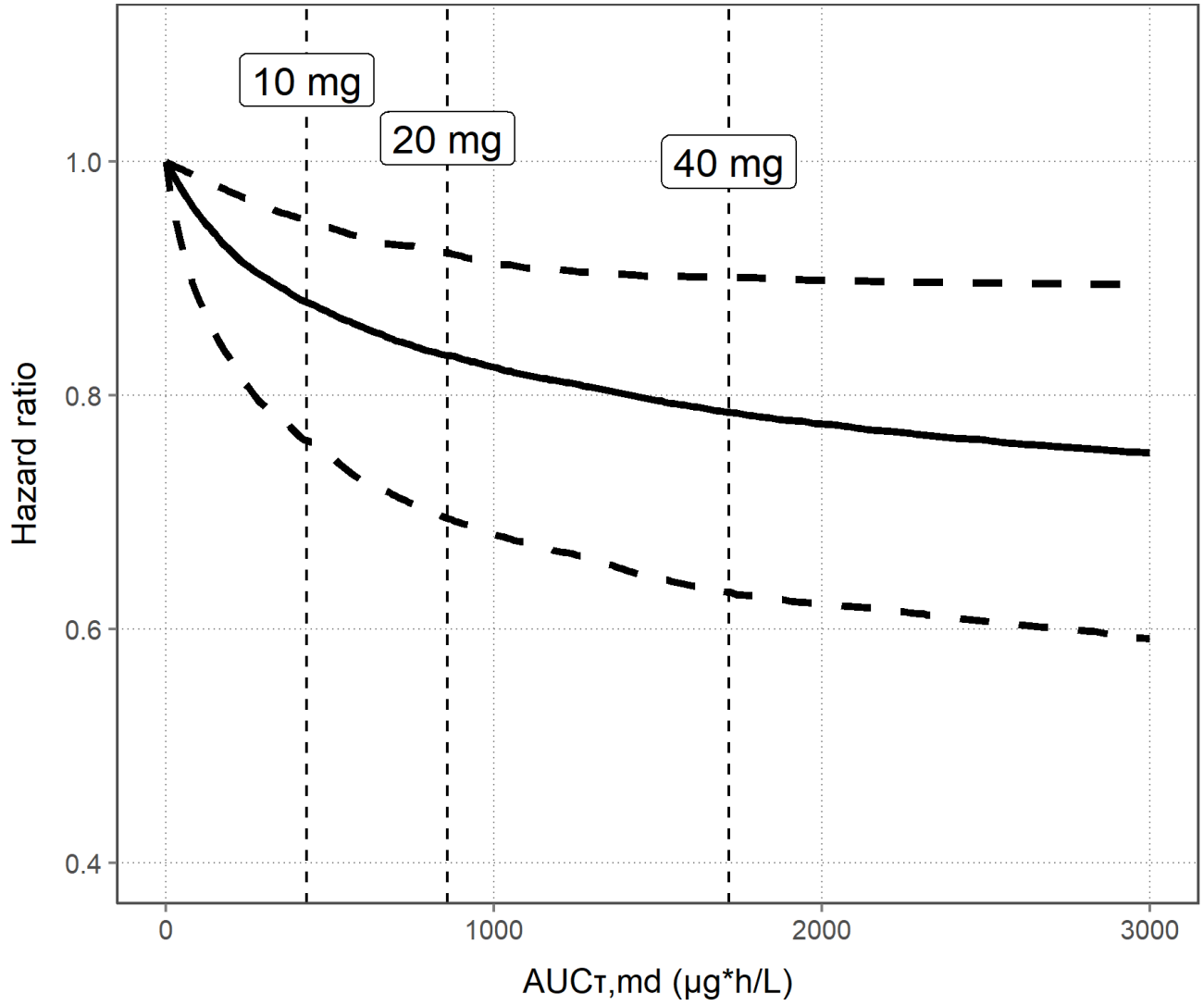


Dose-exposure and NT-proBNP





Dose-exposure and CV events



Conclusions

- The major determinants of higher finerenone exposure were lower body weight and lower eGFR
- Due to protocolized finerenone dose titration, higher doses did not lead to higher serum potassium concentrations
- Higher finerenone exposure was associated with a non-significant lower frequency of CV events and significantly greater reduction in NT-proBNP
- These data are consistent with prior results from CKD & T2DM, and should provide reassurance for appropriate prescribing and titration of finerenone in HFmrEF/HFpEF

Acknowledgements

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