

win ratio: the CanCovDia study

dossier: me20Donath2

services: .consulting (Alexandra, Sina)

.regulatory (David, Claudia, Bettina, Kristin)

.statistics (Marco)

Canakinumab in patients with COVID-19 and type 2 diabetes – A multicentre, randomised, double-blind, placebo-controlled trial

Matthias Heprich,^{a,1} Jonathan M. Mudry,^{a,1} Claudia Gregoriano,^b Francois R. Jornayvaz,^j Sebastian Carballo,ⁱ Anne Wojtuszczyzn,^l Pierre-Alexandre Bart,^g Jean-Daniel Chiche,^k Stefan Fischli,^h Thomas Baumgartner,^m Claudia Cavelti-Weder,^m Dominique L. Braun,ⁿ Huldrych F. Günthard,ⁿ Felix Beuschlein,^m Anna Conen,^c Emily West,ⁿ Egon Isenring,^b Stefan Zechmann,^a Gabriela Bucklar,^a Yoann Aubry,^a Ludovic Dey,^f Beat Müller,^b Patrick Hunziker,^d Philipp Schütz,^b Marco Cattaneo,^e and Marc Y. Donath^{a}*

www.thelancet.com Vol 53 November, 2022

eClinicalMedicine
2022;53: 101649

Published online 17 September 2022

<https://doi.org/10.1016/j.eclinm.2022.101649>

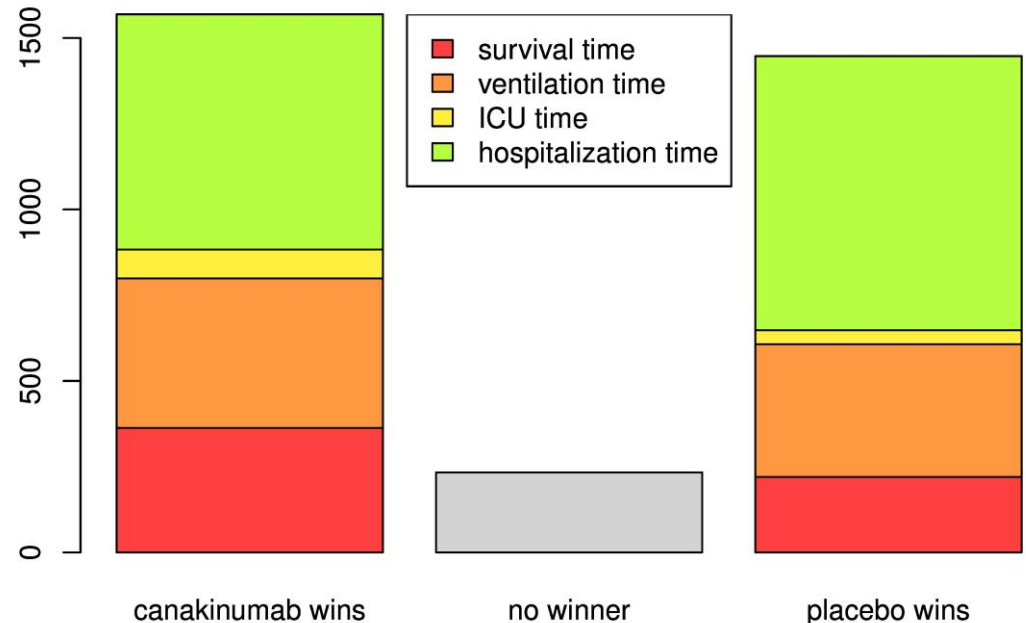
Interpretation In patients with type 2 diabetes who were hospitalised with COVID-19, treatment with canakinumab in addition to standard-of-care did not result in a statistically significant improvement of the primary composite outcome. Patients treated with canakinumab required significantly less anti-diabetes drugs to achieve similar glycaemic control. Canakinumab was associated with a prolonged reduction of systemic inflammation.

win ratio: the CanCovDia study

components of primary endpoint:

1. survival time
2. ventilation time
3. ICU time
4. hospitalization time

Pocock et al. (2012). The win ratio: a new approach to the analysis of composite endpoints in clinical trials based on clinical priorities. Eur Heart J 33:176–182.



unmatched win-ratio approach:

- all 57 canakinumab patients compared with all 57 placebo patients (3249 comparisons)
- comparisons of components of primary endpoint combined in **lexicographic order** (winner determined by **first component** in which patients were *known* to differ, up to 4 weeks after study treatment)
- win ratio (number of canakinumab wins divided by number of placebo wins): 1.08, 95% CI [0.69,1.69], $p=0.72$