Anémie péri-opératoire

ID: 508

Efficacy of iron isomaltoside to prevent anaemia and improve Patient-Reported Outcome Measures (PROMs) after total knee arthroplasty. Preliminary results.

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Position du problème et objectif(s) de l'étude:

Background and Objective:

Total knee arthroplasty (TKA) is widely associated with postoperative anaemia wich is known to increase morbidity and mortality. While intravenous iron supplementation corrects biological markers of anaemia(e.g. haemoglobin (Hb), iron status...), clinical impact needs further investigation in order to assess the quality of recovery like PROMs after major orthopaedics surgeries.1,2

Matériel et méthodes:

After IRB approval (number: 707, study number 2022/92), study registration (EudraCT number 2022-001252-41), and patient informed consent, between September 2022 and March 2023, 18 anaemic patients (Hb < 13g.dL-1) scheduled for total knee arthroplasty under spinal anaesthesia were prospectively enrolled in this monocentric, double-blind, randomised, controlled trial. Patients were allocated into group placebo receiving 250mL of 0.9% sodium chloride, and group iron receiving 1g of 50mg.mL-1 iron isomaltoside added with 230mL of 0.9% sodium chloride. A blind observer noted the evolution of the functional recovery (QoR-15) and Fatigue Severity Scale (FSS) the day before surgery and post-operatively at day-1, day-3, day-7, day-15, and day-30. Blood sampling was performed pre-operatively as well as on day-3 and after 6 weeks to support our results. Data were analysed using Mann-Witney U and Generalized Linear Mixed Model tests (GLMM), as appropriate.

Résultats & Discussion:

Preliminary results highlight no statistically significant difference between groups regarding the QoR-15 at day-15 [mean (SD); placebo: 110.2 (24.8); iron: 125.5 (21.8); p = 0.2]. According to GLMM analyses, neither main effect of group nor interaction between group and time was significantly different concerning QoR-15 (F(1,9) = 0.00; p = 0.985 and F(3,23) = 0.77; p = 0.5, respectively), and FSS (F(1,11) =

0.53; p = 0.481 and F(2,27) = 0,21; p = 0.852, respectively). Hb (g.dL-1) drop between day-1 and day-42 was significantly different [mean (SD); placebo: -0.8 (0.9) and iron: 0.5 (1.1); p = 0.014].

Conclusion:

Conclusions:

Iron supplementation reduces postoperative anaemia but does not improve PROMs when compared to placebo. Nonetheless, these results should be confirmed once the total trial sample-size (46) will have been achieved.

Références bibliographiques:

1 Yoo S et al. Eur J Anaesthesiol. 2021;38(4):358-365. 2 Rohrer F et al. Eur J Anaesthesiol. 2021;38(11):1209-1210.

150- 100- QoR-15 50- 0-		Iron Placebo				
_	Day-1	Day-1	Day-3	Day-7	Day-15	Day-30
Group placebo: EMM	121	110	118	110	119	134
95% CI	103 - 139	89 - 131	103 - 132	92 - 128	100 - 137	121 - 146
Group iron: EMM	126	107	122	114	115	126
95% CI	106 - 146	84 - 130	106 - 138	95 - 134	95 - 136	112 - 140
Mean difference	-4.8	3,4	-4.2	-4.1	3.3	7.5
95% CI	-31 - 22	-28 - 34	-26 - 18	-31 - 22	-25 - 31	-11 - 27

Note : Estimated Marginal Means (EMM)

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