



This pilot study showed no statistically significant treatment effect from fluid administration, but does not exclude the possibility of a clinically important treatment effect” Jones et al (2018).

Abstract:

Study objective: The objective of this pilot study is to assess the feasibility and necessity of performing a large-scale trial to measure the effect of intravenous fluid therapy on migraine headache pain.

Methods: This was a single-center, pilot randomized controlled trial. We randomized adult emergency department migraine headache patients to receive 1 L of normal saline solution during 1 hour (fluid group) or saline solution at 10 mL/hour for 1 hour (control group). All patients received intravenous prochlorperazine and diphenhydramine at the start of fluid administration. Participants and outcome assessors were blinded; nurses administering the intervention were not. Outcomes were assessed at 60 and 120 minutes, and 48 hours. The primary outcome was the difference in the verbal pain rating (on a scale of 0 to 10) between 0 and 60 minutes. Key secondary outcomes included additional clinical endpoints, the rate of protocol completion, and the effectiveness of blinding.

Results: Fifty patients consented to participate; one withdrew, leaving 25 patients randomized to the fluid group and 24 in the no fluid group. The mean improvement in 0- to 60-minute pain score was 4.5 (95% confidence interval 3.7 to 5.3) in the fluid group and 4.9

(95% confidence interval 3.5 to 6.2) in the control group. Primary outcome data were collected for 49 of 50 enrolled patients, and only one participant correctly identified the group assignment.

Conclusion: This pilot study showed no statistically significant treatment effect from fluid administration, but does not exclude the possibility of a clinically important treatment effect. The study protocol and approach to blinding are both feasible and effective.

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### Reference:

Jones, C.W., Remboski, L.B., Freeze, B., Braz, V.A., Gaughan, J.P. and McLean, S.A. (2018) Intravenous Fluid for the Treatment of Emergency Department Patients With Migraine Headache: A Randomized Controlled Trial. *Annals of Emergency Medicine*. October 26th. .

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