Aim: To show the effect of OMT on LOS and daily weight gain in a sample of premature infants.

Methods: Randomised controlled trial on preterm newborns admitted in a single neonatal intensive care unit (NICU) between 2008 and 2009. A total of 101 subjects free from medical complications and with gestational age > 28 and < 38 weeks were enrolled and randomised in two groups: study group ($N = 47$) and control group ($N = 54$). All subjects received routine paediatric care and OMT was performed in the study group for the entire period of hospitalisation. End points of the study included differences in LOS and daily weight gain. Statistical analyses were based on univariate tests and multivariate linear regression.

Results: Univariate statistical analysis showed no significant imbalances among treated and control groups in terms of main characteristics measured at admission. At the end of follow-up, statistically differences were found between the primary outcome (LOS) and gender, gestational age, birth weight, milk volume at admission and OMT, whilst the secondary outcome (daily weight gain) was associated with gestational age and birth weight. After adjusting for all potential confounders, multivariate analysis showed a significant association between OMT and LOS reduction (mean difference between treated and control groups:–6.325 95% confidence interval (CI)–8.687 to–3.962, $p < 0.0001$). OMT was not associated with any change in daily weight gain.

Conclusions: The present study suggests that OMT plays an important role in the management of preterm infants' hospitalisation.

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OP-153

Is the placebo effect revealable in newborns? Results from an RCT in osteopathy

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Background: The placebo effect has been largely studied and debated in medicine. Interestingly, the majority of studies focussed on children and adults but not on newborns. In the field of osteopathic medicine, few studies documented this effect using sham therapy. A previous study showed the association between osteopathic manipulative treatment (OMT) and length of stay (LOS) on newborns. However, no research was conducted on the placebo effect on newborns osteopathically treated.

Aim: The aim of this study was to detect the association between placebo treatment and change in clinical outcome in newborns.

Methods: A double-blinded randomised control trial was carried out on 250 preterm newborns, gestational age (GA) > 29 and < 37 weeks and free of medical complications. After enrolment, all subjects were randomly assigned to a study group ($N = 107$) and a control group ($N = 143$). All preterms received routine paediatric care and osteopathic sham therapy was administered to the study group only for the entire period of hospitalisation. Primary outcome was to evaluate the effectiveness of sham therapy in reducing LOS.

Results: At entry, univariate statistical analysis showed no differences between groups. At the end of the study, after adjusting for all potential confounders, generalised linear model analysis showed no difference on the primary outcome (mean difference between the study and the control groups: 2.444 95% confidence interval (CI)–0.447, 5.337 $p = 0.09$).

Conclusion: This study is the first in the field showing no effect of placebo treatment using sham therapy on newborns, opening discussions about the age when the placebo effect starts.

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OP-154

Oscillococcinum for influenza treatment

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Aim: The aim of this brief note was to analyse the currently available literature of the popular medicine Oscillococcinum(r) for the treatment of influenza, influenza-like syndromes.

Materials and methods: Oscillococcinum(r) is a unique, original and patented homeopathic medicine produced by Laboratoires Boiron. This paper reports and discusses in detail the currently available scientific literature dealing with Oscillococcinum(r) (moreover, we focussed only on Oscillococcinum(r) and not on Oscillococcinum-like preparations), clarifying certain fundamental aspects of this pharmacological treatment. We evaluate the levels of evidence and strength of recommendations according to the Scottish Intercollegiate Guidelines Network (SIGN) and to Natural Standard.

Results: When assessing medical interventions, there is no general consensus as to the quality criteria for classifying clinical data in terms of treatment outcomes, scientific strength and reliability, and this is particularly true for homeopathic medicines. There exists a hierarchy of methods, associated with progressively better and hence more rigorous evidence-based medicine for aiding clinical decisions. However, in this analysis we have relied exclusively on the most rigorous 'conventional' criteria for evaluation.

Conclusions: In the light of the reported findings, and applying the rigorous criteria of evidence-based medicine, we suggest that Oscillococcinum(r) should be placed in Strength of recommendations category 'B' (as it would be inappropriate to always recommend the specified procedure or intervention, on account of the still existing doubts, but it should be anyway carefully considered) and in Evidence type category 'I' (since there is evidence derived from multiple controlled randomised clinical trials and one systematic review of randomised controlled trials).

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