

RESEARCH

The effects of osteopathic care on autonomic nervous system markers of hospitalized very preterm infants: protocol for a randomized clinical trial



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Osteopathy takes a first step in neonatal research in Belgium. With this protocol for a randomized clinical trial, we want to inform the profession regarding the methodology of the study and ask for its support.

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Background

Premature infants are at risk of suboptimal development of their autonomic nervous system (ANS) since the latter, still immature, develops while being submitted to numerous stressors.^{1,2} This alteration of the nervous system can have systemic, but also behavioral and social consequences.²⁻⁴ Several studies in neonatology have shown beneficial effects of osteopathic care, including a reduction of length of stay and hospital costs in preterm infants.⁵⁻⁹ Through gentle and slow touch and its action on the ANS via stimulation of mechanoreceptor fibers, osteopathic care has shown beneficial physiological effects, such as a decrease in heart rate value, an increase of SpO₂ value and a modulation of HRV.^{7,9-14} The positive effect on the ANS could allow a reduction in the inflammation level and a normalization of

the stress response, improving health outcomes of preterms and their development.^{15,16}

Further research in different settings is needed to better document the mechanisms underlying the results observed so far and to generalize them.

The objective of this study is to investigate the effects of osteopathic care compared to sham treatment on autonomic nervous system markers, i.e. cerebral oxygen saturation (rScO₂), heart rate variability (HRV), peripheral saturation (SpO₂), heart rate (HR), respiratory rate (RR), as well as the clinical evolution of hospitalized very preterm infants. This first RCT with preterms carried out in Belgium will enrich the knowledge in this field and thus contribute to the general approach of evidence-based practice.

Materials and methods

An estimated total of 130 very-preterms infants will be recruited from the CHU of Liège, University Department of Neonatology (Citadelle Hospital Centre). An interim statistical analysis will be carried out after the first 20 subjects to adjust the sample size.

Inclusion criteria:

- » newborn hospitalized in the neonatology department of the Citadelle Hospital Centre;
- » osteopathic care referral by a neonatologist;
- » gestational age (GA) between 28_{0/7} and 31_{6/7};
- » birth weight above the 3rd percentile;
- » informed consent to the child's participation in the study by the parents or legal guardians.

Exclusion criteria:

- » newborn presenting severe respiratory or hemodynamic instability;
- » diagnosis of heart disease;
- » diagnosis of syndrome or genetic anomaly;
- » surgery less than a week ago;
- » diagnosis of high-grade intraventricular

- hemorrhage (equal to or greater than 3);
- » presenting a current infection;
- » HIV-positive mother or drug addiction or experiencing medication withdrawal symptoms;
- » being treated for hypothermia;
- » undergoing invasive ventilation;
- » suspected or proven abdominal obstruction or severe malformation (incompatible with life).

Participants will first be stratified according to their gender (female or male), GA (28_{0/7} to 29_{6/7} or 30_{0/7} to 31_{6/7}) and current respiratory assistance (present or absent) and then randomly assigned into one of the two intervention groups under study, either the osteopathic care intervention (group A: experimental) or the sham intervention (group B: control).

In addition to basic care, the experimental group will receive one consultation of osteopathic care of 20 to 30 minutes, including assessment and treatment, while the control group will receive one sham intervention lasting 25 minutes.

Experimental group

Osteopathic care will be based on the NAME Model 17 and the Ne-O Model.⁶ These models are standardized and safe treatment and assessment protocols designed specifically for premature infants. During the intervention, preterms will lie in a supine position.

Evaluation

The first step of the overall evaluation of the preterm is based on the NAME model: by placing one hand on the sacrum and the other on the skull, the osteopath assesses how the body responds overall to mild compression and mechanical distention. He then quantifies the quality of resilience and tissue homogeneity by giving a numerical rating from 1 to 9 (1 to 3 is poor / 4 to 6 is marginal / 7 to 9 is good).¹⁷ A more specific evaluation is then performed according to the Ne-O Model with respect to the cranium (sutures and condyles), spine, pelvis and lower limbs, upper limbs, rib cage, diaphragm (domes and pillars), viscera, thorax/mediastinum and at the abdominopelvic region. The specific evaluation of each body part is done using four criteria defined under the term TART: 1) Tissue alteration 2) Asymmetry 3) Range of motion 4) Tenderness. These criteria make it possible to determine which body parts require intervention.⁶

Treatment

Techniques recommended in the Ne-O Model are indirect techniques, such as Balanced Ligamentous Tension (BLT) for the body and

Balanced Membranous Tension (BMT) for the cranium.^{5,6,9,18,19} The osteopath(s) in charge of osteopathic care have at least five years of experience in paediatrics, participated in practical training related to the NAME and Ne-O model and received approval from Citadelle Hospital.

Control group

The sham treatment is elaborated according to the TEA model and will resemble the osteopathic intervention as much as possible.²⁰ The professional performing the sham treatment will move his hands over the preterm's body with mild pressure and in a sequence similar to the osteopathic care intervention, but will not use osteopathic techniques and will touch without therapeutic intention.

In addition to the vital parameters mentioned above, the following sociodemographic data will be collected: sex, GA, corrected age at the time of recruitment, birth weight, context of birth, mode of delivery, instrumentation, context of feto-maternal infection, APGAR, age and state of health of the mother (presence of diabetes, hypertension, etc.), exposure to opioids, corticosteroids or narcotics, type of milk, the time required before full enteral feeding as well as full oral feeding, ventilation (number of days on invasive and non-invasive ventilation, oxygen requirements, weaning from oxygen requirements), the presence of sepsis or enterocolitis during hospitalization (exposure or not to antibiotics), as well as the occurrence of cerebral hemorrhage or white matter pathology on transfontanelar ultrasound.

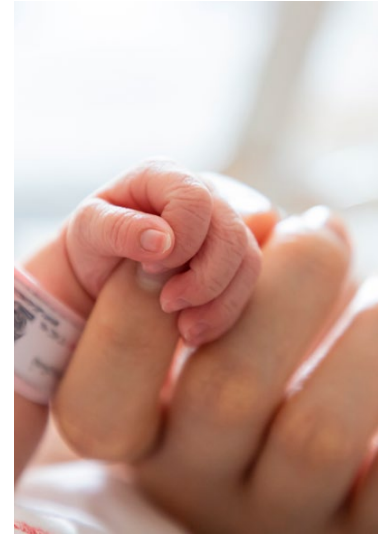
The primary outcome measures will be the mean difference in regional cerebral oxygen saturation (rScO₂) between both groups.

The secondary outcomes will be:

- » The difference in average HRV between group A and B;
- » The difference in average SpO₂ between group A and B;
- » The difference in average HR between group A and B;
- » The difference in average FR between group A and B;
- » The correlation between average rScO₂ and average HRV;
- » The correlation between average rScO₂ and average SpO₂;
- » The characteristics of clinical evolution between group A and B.

Vital data will be extracted from the computerized patient file over different time windows before and after the osteopathic/sham treatment:

1. during an interval of 5 minutes before treatment;
2. during the treatment, lasting 20 to 30 minutes;
3. during an interval of 20 minutes, immediately after;
4. during an interval of 5 minutes, 24 hours later (+ or – one hour).



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The standard deviation between the two groups will be measured regarding the following general characteristics: birth weight, the type of ventilation, feeding mode. The statistical significance threshold will be set at $p < 0.05$ for all inferential analyses with a power of 0.8.

Trial Status

Ethical Committee approval

The current protocol was evaluated by an independent ethics committee: the ethics committee of the University Hospital Faculty of Liège, which issued a favourable opinion after consultation with the ethics committee of Citadelle Hospital on 20 March 2024.

Funding

Currently, no funding sources have been confirmed. Estimated cost between €15,000 and €20,000, including €13,000 for the cerebral oxygen saturation devices.

Human resources

The research team is still looking for French-speaking osteopaths with at least 5 years of experience in neonatology and paediatricians who want to actively participate in this project. If interested, please contact Jo-Annie Landry: joannielandry@yahoo.ca

Registration publication plan

The protocol will be registered and published on ClinicalTrials.gov. Finally, the results will be published between June and December 2026.