Study Title:

Effectiveness of Repositioning, Physical Therapy, and Cranial Remolding in Infants With Cranial Deformation

Investigators:

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Study Protocol

The proposed study will have a similar set-up and examination as the Steinburg[1] study but will also expand upon it by reporting the length of time needed for repositioning to achieve a normalized head shape. Since the American Academy for Pediatrics recommends head shape to be assessed at the 2 month well-child visit, the age of initiation for this study will be 2 months(with the following exception: per sponsor's approval, an infant who is already 3 months of age but able to get all study evaluation procedures complete within 3 weeks of turning 3 months of age – i.e. the infant is less than 3 months and 21 days of age – may be included as it does not affect the integrity of the data within the study). After achieving IRB approval for the study, local pediatricians can begin to refer patients at their 2 month well-child visit. At the evaluation appointment, caregivers will learn about this research and choose if they wish to consent their child to the study protocol. After consent, a scan and measurements of their infant will be taken, neck range of motion (ROM) assessed, and specific repositioning strategies discussed targeted at correction of their child's deformational head shape. The initial appointment is expected to take about 1 hour. Follow up appointments are expected to take 30 minutes and all appointments will be conducted by a certified and licensed orthotist who has been trained in repositioning strategies and cranial remolding therapy.

In this proposed study, each child will attempt repositioning strategies for at least 2 months or until the head shape is considered mild enough not to need CRO treatment. If after 2 months of repositioning, the head shape is still considered moderate or severe, the caregivers will be given the option to either 1) be treated with a CRO (which will be provided free of charge) or 2) continue repositioning efforts. This option will again be given at 5 months of age and 6 months of age. Throughout the study, the caregivers of the repositioning patients will be re-instructed and the child re-examined at each monthly visit by a qualified orthotist. A survey of compliance will also be administered at these visits. Quantitative measurements of cranial improvement or worsening will be given to the caregivers at these visits via caliper measurements and a non-invasive scan. Frequent re-evaluations are expected to increase compliance with the repositioning efforts. If developmental delay or lack of neck ROM is noted, the caregivers will be encouraged to seek physical therapy for their infant. Patients undergoing cranial remolding treatment will be seen every 1-4 weeks (depending on growth) and measured/re-evaluated every 6-8 weeks. The reason caregivers will be given a choice at 4,5, and 6 months of age to initiate CRO treatment is because several studies have suggested CRO treatment is most effective when started by 6 months of age[1,2,9,10]. Several studies have also stated that the younger the patient, the more effective repositioning strategies are at correcting cranial shape[1,2,9]. This methodic appointment scheduling process is more fully detailed in the attached flow chart. Upon discharge from treatment (either due to correction of the deformational head shape or "aging out" at 12 months), the child will once again be scanned and measurements recorded. By analyzing this data, the effectiveness of repositioning and CRO treatment can be determined for this patient population. The surveys will also be reviewed for compliance.

The overall success rate of repositioning (returning the head shape to mild or normal shape) will be expressed as a percentage of the study group. The successful groups will be further divided into subsets to show the severity at initiation as well as the number of months needed for correction through repositioning or CRO efforts. This will aid in determining if certain severities are more prone to failing repositioning/CRO treatment and how long repositioning/CRO treatment efforts typically take to resolve a deformational head shape. It is anticipated (based on prior clinical experience) that not all caregivers will choose to proceed with CRO treatment by 6 months of age, which will result in a subset of patients who continue with repositioning efforts until a maximum of 12 months of age. Most private insurance recommend at least 2 months of repositioning efforts before proceeding with CRO treatment. This study is expected to support if this is an adequate amount of time for reporting successful or failed repositioning efforts. For those who choose CRO treatment by 6 months of age, the treatment time and success rate will be reported similarly.

Torticollis Sub-study Protocol:

Once an infant is enrolled in the study he/she will be seen for an evaluation by a certified orthotist, which will include a cranial scan and measurement of cranial asymmetry. Since cranial asymmetry is often associated with torticollis, each infant will also see a physical therapist who will assess head and trunk posture, and active and passive neck range of motion. The physical therapist will also screen the infant to rule-out problems known to occur with torticollis, such as a delay in developmental milestones. If an infant is found to have a delay in motor milestones, he/she will be sent back to the referring physician

Infants who have restrictions in neck range of motion will receive weekly physical therapy services provided by a licensed physical therapist. Physical therapy treatment will follow the evidence-based practice guidelines describe by Kaplan, Coulter and Fetters (2013). These include neck passive range of motion, neck and trunk active range of motion, and development of symmetrical movement. Parents/caregivers will received instructions and a handout on how to carry out neck range of motion and strengthening exercises at home. They will also receive written information on easy environmental adaptations that can be made to prompt the infant to turn his/her head in the direction of the muscle tightness. Parent/caregiver recommendations will be reviewed at each treatment session. A compliance survey will also be administered at each follow up visit.

Standard, noninvasive, physical therapy procedures will be used to evaluate the infants cervical rotation and lateral neck flexion range of motion using an arthrodial protractor, goniometer or inclinometer, depending on which motion is being measured. The Muscle Function Scale will be used to assess neck muscle strength. The Albert Infant Motor Scale (AIMS), which is an observational screening tool, will be used to assess motor milestones. There is minimal/ no risk associated with these tests.

3-D Imaging Sub-study Protocol:

A target of 50 normal, healthy infants will be recruited to create a control group. These infants will be evaluated by an Orthotist and Physical therapist at 2 months of age in the same manner as the affected infants; however, these infants will only be included if shown to lack significant cranial deformational and lack the need for physical therapy intervention. They will undergo a 3dMD scan at 2, 6, and 12 months of age (3 appointments total). The intent is to create a control group in order to determine if the affected infants in the full study have growth patterns that differ from the normal evolution of the cranial shape. The infants will be re-evaluated at 12 months of age to confirm inclusion criteria. There is minimal/ no risk associated with the tests performed on the healthy subjects.

In summary: normal subjects will undergo minimal-risk procedures only for the purpose of this study at 2, 6, and 12 months of age: head shape evaluation by an orthotist, physical therapy evaluation by a licensed Physical Therapist, questionnaires, and 3dMD scans.

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