STUDY PROTOCOL

Official title: A Pilot Study - to observe the effects of the Serkel cranial remolding orthosis on infants with deformational head shapes, a pre-market fitting

NCT number: NCT06831513

IRB Approved Document date: 07-21-22

Form A

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PROTOCOL FORM / RESEARCH DESCRIPTION

If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

Click once on the highlighted entry in each box to provide your response. Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

1. Purpose and objectives. *List the purpose and objectives:*

This is a pre market fitting of a new brand of cranial remolding orthosis. Cranial remolding treatment is already an accepted treatment for deformational head shapes within the United States. In 2021, the FDA approved the first 3D printed cranial remolding orthosis. We are fitting a new to US market 3D printed cranial orthosis, which has not yet been FDA approved. The orthosis is nearly identical to existing FDA approved devices. It is currently being used in Australia. Would like to determine the functionality of this new type of helmet.

2. Background.

- Describe past experimental and/or clinical findings leading to the formulation of your study.
- For research involving investigational drugs, describe the previously conducted animal and human studies.
- For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.
- Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (section number and/or title) or if none, ensure background includes references.

Please respond to all components of this item, or clearly indicate which components are not applicable.

a. Background

The cranial remolding orthosis (CRO) that will be used is 3D CRO fabricated by the company Serkle. Serkle is an Australian company seeking to introduce their orthoses to the American market. Cranial remolding treatment is already an accepted treatment for deformational head shapes within the United States. In 2021, the FDA approved the first 3D printed cranial remolding orthosis. We are fitting a new to US market 3D printed cranial orthosis, which has not yet been FDA approved. The orthosis is nearly identical to existing FDA approved devices.

b. Current practice

Cranial remolding orthoses are used to treat deformational plagiocephaly. After receiving a plagiocephaly diagnosis from a physician infants from the age of 3 months to 18 months can be fitted with a cranial remolding orthosis. The orthosis is worn 23 hours a day and while the child grows the helmet guides the growth to prevent/reduce head shape asymmetry's. This is standard of care. There are also another method that is considered standard of care for more mild cases of deformational plagiocephaly and this is repositioning. Repositioning is when the caregiver of the parent constant repositions the infant to prevent him or her from lying in their flat spot.

3. Study Design.
Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

This is a pre-market fitting of a cranial remolding orthosis. There will be no data collected or published through this. Serkel, the manufactures of the cranial remolding orthosis, may be provided information on the success of their device. Parent/caregivers will be provided all information regarding the new cranial remolding orthosis. Through the informed consent: 1) they will be aware this specific orthosis is not yet a FDA approved orthosis, 2) there are similar orthoses approved on the market 3)they will be

provided the risks of the orthosis, 4) they will be provided benefits of the orthosis. Qualified Orthotist, trained and certified in fitting CROs will see those participating in the pre market fitting and standards of care will be provided.

4. Research Plan / Description of the Research Methods:

4.a. Provide a **comprehensive narrative** describing the **research methods**.

1) Provide the **order in which tests/procedures will be performed**,
2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.
3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Please respond to all components of this item, or clearly indicate which components are not applicable.

1) Infants with the diagnosis of plagiocephaly will be referred by their pediatrician for evaluation to be fit with a cranial remolding orthosis. Infants will be evaluated and if deformational plagiocephaly is present and treatable by CRO, parents/caregivers will be provided the option to be fit with a traditional CRO or the pre-market fitting CRO. Benefits and limitations will be provided for each. Parents/caregivers will be provide time to consider and think about both options. Should they decide for their child to be treated with a pre-market CRO. They will be provided and will review the informed consent together. Once informed consent is received, infant's head will be scanned and CRO will be fabricated. 1 week later they will be fitted with CRO. And will be followed up with 1-2 week after that. After initial (1-2 week) follow up, will follow up every 3 weeks. (this is standard of care)
2) All of the appointments (the evaluation, fitting, follow ups) will be held in the UTSW Prosthetics Orthotics clinic in a private patient room. Documentation will be done in Epic. Scans, pictures, and measurements sheets will be stored in a protected folder on Microsoft teams.
3) Serkel will be providing limited amount (18) of pre-market helmets for no cost. This determines the size of our sample, approximately 18 subjects, up to 25 max.
4) Data collected will be cranial measurements, scans, and photos. This data will not be published, but remain in the patient chart. (this is standard of care procedures). Serkel manufacture is requesting initial and final cranial measurements/ratios (de-identified data).

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4.b. List of the study intervention(s) being tested or evaluated under this protocol

☑ **N/A -** this study does not test or evaluate an intervention. Skip to item 4.d.

#	Study intervention(s) being tested or evaluated under the protocol *Add or delete rows as needed*	Affiliate Place a check next to institution(s) where the intervention will be performed	Local Standard Practice? Indicate whether the intervention is considered acceptable practice locally for applicable institutions
1	Insert study intervention 1 here	☐ UTSW	☐ Yes
		☐ PHHS	☐ Yes
		☐CMC	☐ Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes
2	Insert study intervention 2 here	☐ UTSW	☐ Yes
		☐ PHHS	☐ Yes
		☐CMC	☐ Yes
		☐THR	☐ Yes
		☐TSRH	☐ Yes
		☐ Other: _____	☐ Yes

4.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)

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4.c.
Study Intervention #1
Insert name used in 4.b.

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc) **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".

If you are requesting a Waiver of Informed Consent, complete the table below.

If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**

List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting.

	Not serious	**Serious**
Likely These risks are expected to occur in more than **20** out of **100** subjects.	•	•
	Not serious	**Serious**
Less likely These risks are expected to occur in **5-20** subjects or less out of **100** subjects.	•	•
		Serious
Rare These risks are expected to occur in less than **5** subjects out of **100**		•

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		Serious
Rare These risks are expected to occur in less than **5** subjects out of **100**		•

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	4.d. List ALL other research procedures or components not listed in table 4.b. ***The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.*** Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments)			
#	**Research component** • **individual procedures** *example:* **Eligibility Assessments** • History and physical • Questionnaire • Laboratory tests *Add or delete rows as needed*	**Column A** **Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the study.**	**Column B** **Research Only** Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if they were not participating in the study)*	**Column D** **Risks** **If you are requesting a Waiver of Informed Consent, complete the table below.** List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate: • Serious and likely; • Serious and less likely; • Serious and rare; • Not serious and likely; • Not serious and less likely
1				

	This a pre-market fitting of a cranial remolding orthosis: • Physicians order • Diagnosis of deformational plagiocephaly • Infant is over 3 months of each Cranial Asymmetry must be moderate, or fall within the standard guidelines to facilitate the necessity of a CRO.	• Evaluation – visual, pictures, scans. (standard of care) If child meets requirements and CRO treatment is appropriate, will discuss purpose of CRO and provide parents/caregivers with details (benefits/limitations) of traditional CRO design vs pre-market 3D printed CRO. Review informed consent together, allow parent/caregivers time to review and discus information amongst themselves • If they choose to proceed, scan and fabricated CRO (standard of care) • See back in 1 week for fitting (standard of care) • See back in 1-2 weeks for initial follow up (standard of care) • See back every 3 weeks for follow up (standard of care)	**This is a pre-market fitting of a 3D printed cranial remolding orthosis. No research will be performed.**	
	Insert procedure here			
	Insert procedure here			
2	**Insert component 2 here**			
	Insert procedure here			
	Insert procedure here			
	Insert procedure here			
3	**Insert component 3 here**			
	Insert procedure here			
	Insert procedure here			
	Insert procedure here			
4	**Insert component 4 here**			
	Insert procedure here			
	Insert procedure here			
	Insert procedure here			

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5. Safety Precautions. *(Describe safeguards to address the serious risks listed above.)*

a. Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

Those participating in pre-market fittings will be followed up with every 3 weeks and will have access (phone number and email) to contact treating clinician at all times. (this is standard of care)

b. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

Should reaction occur that cannot be treated by Orthotist, the patient will be instructed to discontinue wearing the orthosis and referring physician will be contacted. If reactions are in need of immediate attention, will advise patient's parents/caregivers to discontinue wearing CRO and to go to urgent care.

c. Will the safeguards be different between/among groups?

☐ Yes ☑ No This is not applicable, we not comparing groups

If yes, describe here