NATIONAL CENTER FOR MATERNAL AND CHILD HEALTH, MONGOLIA

STUDY INFORMATION SHEET

Traditional Mongolian Swaddling and Developmental Dysplasia Of The Hip: A Randomized Controlled Trial

Lead Researcher

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- You are **being asked** to participate in a research study to test the effect of traditional Mongolian swaddling on developmental dysplasia of the hip i.e. problems with the way a baby's hip joint forms.
- Your babies are eligible to participate in this study if your baby has been diagnosed with **physiologically immature** (Type 2a) hip(s) at birth during the hip ultrasound screening.
- **The research procedures are**: Your newborn babies with physiologically immature (Graf Type 2a) hips will be randomly allocated to one of two groups: "SWADDLING" and "NON-SWADDLING". The "NON-SWADDLING" group will be instructed not to swaddle at all. A research assistant will tell you in which group is for your babies. The "SWADDLING" group will be swaddled in the common method. Both groups will be followed up by hip ultrasound at 4-6 weeks' intervals until healing. All infants in need of therapy (Graf type 2a-, 2c or worse) will be treated with a splint. At around 12 months of age all children will be checked again by hip ultrasound.
- There are **no possible risks** for the participants with the study.
- All babies will be examined and **controlled until healing** by an experienced pediatricians' team regularly for free.
- You will **not be compensated** for your participation in this research study.
- All research data collected **will be stored securely and confidentially**. Participating baby will be assigned an ID number to be used during data collection and analysis. All completed study forms will be kept in a secured, locked area under the direct supervision of the principal investigator. Following the study, the paper copies of the Informed consent form will be kept in a locked file cabinet in the office of the principal investigator. At no time will any participant be identified by name in any report, summary, or publication of the data. The data available for analysis will contain only a case number. All paper, examination ultrasound pictures will be stored in a locked filing cabinet at the principal investigator's office. Access to these records will be limited to staff authorized by the principal investigator to handle the documents. These records will be destroyed five years after the completion of the study.
- If you have any comments, concerns, or questions regarding the conduct of this research please **contact the researchers** listed at the top of this form.

Please contact National Center for Maternal and Child Health's Office of Research by phone, **362886**, by e-mail at **baylag.m@gmail**.com if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.