TRADITIONAL MONGOLIAN SWADDLING AND DEVELOPMENTAL DYSPLASIA OF THE HIP: A RANDOMIZED CONTROLLED TRIAL

RESEARCH PROTOCOL

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SUMMARY

Background

In Mongolia , swaddling is an ancient practice and nowadays it still remains common child care in the first months of life. Mongolian traditional way of swaddling technique involves tight, prolonged wrapping from the head or neck down in two to three layers of thin cotton cloth, covered by layers of thick blankets and binding with 2-3 tiers for whole day. This traditional prolonged swaddling where arms and legs are extended and hips are in adduction position might increase the risk for developmental dysplasia of the hip (DDH). DDH is a major health problem that can lead to lifelong disability if diagnosis is missed in first weeks of life. Mongolia is the first Asian country that launched a universal ultrasound hip screening (Graf's method) for DDH in newborns. All DDH cases are followed up on monthly basis by hip ultrasound and treated with a simple extension and abduction orthosis if necessary.

Objectives

To test the effect of traditional swaddling on the DDH in Mongolia

Design

A prospective, randomized trial with two study groups will be conducted in Mongolia. The term newborns with Graf Type 2a (physiologically immature) will be randomly allocated to one of two groups. The intervention/"non-swaddling" group will be instructed not to swaddle at all. The control/"swaddling group" will be swaddled in the common traditional Mongolian method. Both groups will be followed up by Graf's method of hip ultrasound at 4-6 weeks' intervals until healing according to Mongolian national guideline. All infants in need of therapy (Graf type 2a-, 2c or worse) will be treated with Tubinger orthosis. At around 12 months of age all children will be checked again by Graf's method of hip ultrasound.

Timeline and Analysis

The study will be conducted between August 2019-March 2021. Findings will be reported in March-June 2021. Analysis will be intention to treat.

Ethics

The study protocol will be reviewed and approved by the Institutional Review Board at the National Center for Maternal and Child Health and the Ethical Review Committee of Ministry of Health, Mongolia prior to start the study.

1. BACKGROUND AND JUSTIFICATION

Developmental dysplasia of the hip (DDH) belongs to the most common disorders of osteoarticular system with public health priorities in generally otherwise healthy infants. Severity can range from a minor acetabular dysplasia to a complete dislocation. Estimates of the incidence of DDH are quite variable and depend on detection methods, ages of the child, and diagnostic criteria etc.[1-8] A Mongolian study reported that the nationwide hip ultrasound screening by Graf method detected 14.6% of physiologically immature and 1.2% of dysplastic cases.[9] Another prospective study reported 1.3% incidence of DDH by Graf method of ultrasound.[10] DDH is a multifactorial disorder that genetic and non-genetic factors are involved in its etiology. Contribiuting factors for the development of DDH are space (big infants), position in utero and hormonal factors (Relaxin) and genetic predisposition.[11] In addition, postnatal mechanical factors are also important but not studied thoroughly yet.[12]

Fetal hip joint consists of cartilaginous tissue on a osseous basis. During further maturation, the cartilage is subsequently replaced by bone. Studies have shown that hip joints have a considerable potential for maturation even after birth i.e during the first weeks of life.[13,14] These unique features allow detect by ultrasound and treat DDH conservatively during this window of opportunity. The early detection and simple treatment with an extension and abduction orthosis in the first weeks of life mostly leads to a maturation and cure of the hip joints, and subsequently, prevents handicaps in children later in life. However, there is still continuing discussion about whether to screen for DDH.[2,15,16] One point of contention is whether hip joints below the threshold of 60° alpha should be classified as pathological (DDH) or whether a range of physiological immaturity (Graf types 2a / 2a+) is defined where a wait-and-control approach is chosen.[2,15,17] However, these hips may be vulnerable to persistent dysplasia if postnatal mechanical factors such as swaddling are used in child care. Some studies have found that a history of swaddling to be one of the risk factors for DDH.[18-20] Also the swaddling history was more common in late presenting infants with hip dislocation.[21]

In many cultures around the world newborn babies are swaddled to calm them down and fall asleep, and some cultures believe that swaddling can prevent the baby from suffering cold weather especially during winter time. In Mongolia, swaddling is an ancient practice and nowadays it still remains common child care in the first months of life. Mongolian traditional way of swaddling technique involves tight, prolonged wrapping from the head or neck down in two to three layers of thin cotton cloth, covered by layers of thick blankets and binding with 2-3 tiers. However, this prolonged swaddling in the first year of life did not have any significant impact on children's early mental or psychomotor development.[22]

In Mongolia, the Graf's method of hip ultrasound was introduced in 2007 by Swiss-Mongolian Pediatric Project (SMOPP), a private/non-governmental humanitarian aid project, and has subsequently become step by step a nationwide screening program. Trained neonatologists or pediatricians of Maternity hospitals screen all newborns using the Graf's method[23] of hip ultrasound and perform a flexion-abduction treatment, if necessary. The routine guideline is the following: newborns with Type 1 hips are discharged without any further follow-up. Newborns with Type 2a hips are followed up by ultrasound in monthly intervals until these mature. Children who have 2a hips during the course of follow-up are either followed up (Type 2a+), or treated if the hip insufficiently matured (Type 2a-). Children with Type 2c to 4 hips are treated with a Tubingen hip extension and abduction orthosis and also followed up until fully mature. Children

with Type 4 hips that could not be splinted are referred for surgical interventions.[22] Full documentations of all cases is mandatory.

Recent studies in Mongolia showed that 10-15% of newborns have physiological immaturity (Type 2a hip by Graf method) at birth.[8] Given the high prevalence of traditional swaddling in the country, any association with DDH could have large public health implications. We will investigate the effect of traditional tight and prolonged swaddling on DDH in Mongolia in this prospective randomized controlled trial (RCT).

2. OBJECTIVES

Mongolian traditional prolonged swaddling where arms and legs are extended and hips are in adduction position increases the risk for DDH. This hypothesis is going to be tested in this study.

The primary outcomes: The number of "non-Type 1" hip cases at the monthly follow-up ultrasound control visits

The secondary outcomes:

a. number of DDH cases (Graf Type 2a-, Type C, D and Type 4) at any monthly follow-up ultrasound control visits and rim defects at 12 months' follow-up
b. correlation between the primary outcome and the swaddling frequency (in hoursper day) and swaddling duration (in days)
c. primary and secondary outcomes association with the swaddling.

3. STUDY METHODOLOGY

3.1. Study design

A prospective interventional randomized controlled trial with two study groups will be conducted in Mongolia.

"Swaddling" group: The newborns randomized into the "swaddling" group will be swaddled in the common traditional Mongolian method at least 20-24 hours every day for 4-6 weeks. Traditional swaddling in Mongolia is as follows: Swaddling is a tightly wrapping (2 adult fingers pass under the cloth) of a baby in several layers of cloth, covered by one warmer blanket from head and neck to toe in a straight position after birth for day and night time. Two or three ropes are used across a baby's body for binding to avoid unwrapping. Since the non-swaddling clothes have to be provided with alternatives to the readily available swaddling clothes and blankets, the swaddled group will be given a blanket and several cotton sheets at the time of recruitment.

"Non-swaddling" group: The "non-swaddling" group will be instructed not to swaddle at all for 4-6 weeks. The required size and warmth of clothing required to keep a newborn infant warmly clothed will be provided to the family. Also, wide warm sleeping bags that allow free legs movements will be provided to prevent swaddling when go outdoors.

3.2. Sampling and randomization

Study site: The National Center for Maternal and Child Health (NCMCH) is purposely selected as a study site. Approximately 50% of all deliveries in Ulaanbaatar occur in the center and there are about 11,000 live births annually. As the center is a specialized tertiary care level teaching hospital, it is responsible for providing services for follow-up ultrasound controls and treatment of DDH cases in Ulaanbaatar. There are two term-delivery units with 6 neonatologists/screeners, a preterm-

delivery unit with 6 neonatologists/screeners and a pediatric radiology unit with 6 radiologists. Data will be collected from September 2019 to March 2021.

Sample size calculations: The primary outcome of interest is dichotomous (Graf Type 1 or non-Type 1 hips). If we assume that 10% of the subjects on the non-swaddled group has a non-Type 1 hip and it is of clinical relevance only if we observe a 30% (effect size) absolute non-improvement for those on the swaddled group (i.e. 40% of the subjects will have a non-type 1 or worst hip).

For a two-sided test of 5%, a formula to calculate the sample size is given by

$$N \text{ (size per group)} = c * \frac{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}{(\pi_1 - \pi_2)^2}$$

where c = 7.9 for 80% power, and π_1=0.2 and π_2=0.4

For a 80% power, we have N (size per group) = $7.9 * [0.1 (1 – 0.1) + 0.4 (1 – 0.4)]/(0.1\text{-}0.4)^2 = 29$

Hence minimum 29 * 2 =58 subjects are needed.

In order to increase the statistical power, and assuming at least a 20% dropout, it is decided to include about 40 subjects in each group.

Sampling: There are 6 neonatologists/screeners at post-delivery wards of the hospital who perform the hip ultrasound screening. Out of the 6 neonatologists/screeners, one neonatologist will be assigned as a data collector for the study to reduce a baseline diagnostic bias. On the first days after birth, all newborns of the data collector will be screened using Graf's method of ultrasound according to the Mongolian National Guideline.[8] After the screening, we will generate a list of all newborns with Graf Type 2a hips on daily basis. All term newborns with Graf Type 2a cases (physiologically immature) will be eligible for the study.

Subject inclusion criteria

Predefined inclusion criteria will be:

1. Term newborns with confirmed Type 2a hips
2. Parents who are able to return for the scheduled follow-up ultrasound examination during the study period
3. Willing to give informed consent
4. Newborns without any symptoms and complaint

Predefined exclusion criteria will be:

1. Newborns with obvious congenital abnormalities (with clear medical consequences)
2. Newborns with needs for intensive care treatment
3. Newborns with low (2499g or less)
4. Newborns with confirmed non-type 2a hips

Randomization sequence will be created using Excel 2007 (Microsoft, Redmond, WA, USA) with a 1:1 allocation using random block sizes of 4 by an independent researcher with no clinical involvement in the trial. After obtaining the consent from the parents, details of the allocated group will be given on colored cards contained in sequentially numbered and sealed envelopes. These will be prepared by the principal investigator and kept in an agreed location on the post-delivery ward. Randomization will take place before discharge when the data collector/neonatologist gives detailed consultation on usual postnatal care of newborns. Corresponding envelopes will be opened

only after the enrolled newborns completed all baseline assessments and it is time to allocate the intervention. Whereas parents allocated to the swaddling group and the research assistants will be aware of the allocated arm, the outcome assessor/radiologist will be kept blinded to the allocation.

3.3. Data collection and quality control

After a routine standard physical examination on the first day of life, all newborns will be examined by hip ultrasound. The standardized and uniform system of Graf will be used for diagnostics.[22] The hip ultrasound examination will be performed by a trained and experienced neonatologist using an ultrasound machines (GE Logiq series) with a linear array transducer operating on an ultrasound frequency of 7–10 MHz. A Sonofirst® holding cradle and transducer fixation unit (Orthopunkt, Solothurn) will be used to prevent tilting errors and to standardize examination techniques.[14,22] A web-based, password-protected tool, "HipScreen" (WebWaren, Bern, Switzerland)[14] will be used for quality control purpose. The tool enables the screener to upload DICOM files exported from the ultrasound machines. Four images (two per hip side; one of them with measured alpha and beta angles according to Graf), will be required. This will allow continuous and reliable review of hip grading, diagnosis of DDH, and treatment decisions. Trained, on-site experts will check all examinations and promptly send comments to the screener. Discrepancies between expert assessments will be resolved by discussion and consensus.

After identification of all term newborns with Graf Type 2a cases (physiologically immature) of the neonatologist/data collector will be listed and the newborns and their mothers will be undergoing the screening process by research assistants to see whether they meet the inclusion criteria. The parents of the physiologically immature cases will be given oral information about hip dysplasia and study purpose. Consequently, parents will give their oral consent to participate. Those who refuse consent will be registered, but will not be included.

After the randomization of eligible newborns with physiologically immature (Graf Type 2a) hips, the research assistants will explain and give detailed information about the study again to the parents in both "swaddled" and "non-swaddled" groups. The parents will be requested to sign an informed consent form if they agree to take part in the study before they are given an ID number. After the obtaining the written consent form, a brief questionnaire about demographic (e.g. birth date, gender of newborn etc.) and birth related information such as fetal position, birth weight, number of parity and family history of DDH will be filled by the research assistants.

For babies assigned to the "swaddling" group, parents will be instructed to follow a pattern of traditional Mongolian swaddling as described above. For babies assigned to the "non-swaddling" group, parents will be instructed to do not swaddle at all and only use a wide sleeping bag with free leg position.

Trained research assistants will make home visits on weekly basis until the infants are 4-6 weeks of age to check and monitor the compliance of the families by observing the baby during every home visit and collecting retrospectively 24-hour diaries of swaddling and non-swaddling patterns. Also unscheduled visits from monitoring research assistants will be organized to estimate unreported non-compliance conducted for all families 2 to 3 times.

At 4-6 weeks follow up visit, the babies will be checked by Graf's method of hip ultrasound performed by a trained radiologist uninformed about the initial status of the hips. Regardless of the study group, monthly controls will be fixed until complete maturation to Graf type 1 is documented. Families, who did not show up for follow-up will be contacted by phone or home

visit. In cases when the parents will not able/willing to come to the follow-up control visit(s), the PI will visit the family and make the follow-up ultrasound examination at their home using a portable ultrasound device (MicroUs EXT-1H, REV:C). All infants in need of therapy (Graf type 2a-, 2c or worse) will be treated with Tubinger orthosis.

Monitoring: In the non-swaddling group, it is expected that some families would not adhere to their instructions of not swaddling because of grandparents/cultural pressures. To monitor compliance and obtain a measure of exposure, multiple sources of information will be used:

1. A retrospective 24-hour history of swaddling/clothing: will be recorded by research assistants during each weekly home visit through recording the carer's descriptions of the style of dress/clothing/ swaddling and length of each during the past 24-hour within the 24-hour retrospective diaries (a kind of behaviour diary adapted to record swaddling/clothing pattern)
2. Direct observation of research assistants during weekly visits: of the dressing/clothing/ swaddling of each child and discreetly recording observations of the type of baby clothing items that each family washed and hung to dry on the day of visit (available for observation during the majority of visits)
3. Analysis of the 7-days prospective mother's diaries used for sleeping and crying/fussing outcome measure: as mother's own reported behaviour during 2 time periods
4. Unscheduled visits from a monitoring research assistants: in order to estimate unreported non-compliance conducted for all families 1 to 3 times
5. End-study research assistant impressions' questionnaire: of their impression about compliance in each family and the consistency and extent of accuracy of the reports from each family during each week of child's life

For analysis, the first and third methods of exposure recordings above will be quantifiable and will be combined to reveal exposure to swaddling per child for use in per-protocol analysis. The other three methods detailed above will be triangulated with the data from the diaries.

3.4. Outcome assessments

The primary outcome of the study will be the number of “non-Type 1” hip cases at the any monthly follow-up ultrasound control visits.

The secondary outcomes are:

a. number of DDH cases (Graf Type 2a-, Type C, D and Type 4) at any monthly follow-up ultrasound control visits
b. correlation between the primary outcome and the swaddling frequency (in hours) per day and swaddling duration in days
c. primary and secondary outcomes association with the swaddling.

Operational definitions

Swaddled: Newborns are swaddled in the common traditional Mongolian method at least 20 hours per day for 4-6 weeks
Non swaddled: Newborns are not swaddled at all.
The “non-Type 1” hip case: a neonate who’s Graf ultrasound type is other than Type 1 at any monthly follow-up visits
Physiologically immature or Graf Type 2a hip: has a certain degree of physiological delay in ossification of the bony acetabular roof. The alpha angle is between 50 and 59, the beta angle is between 55 and 77, and the patient is younger than 6 weeks of age.

Graf Types 2a- and 2a+: Starting from 55° alpha at 6 weeks of age and assuming a spontaneous maturation of 1° per week. Type 2a+ is still considered to be physiological while 2a- hips are assigned to the group of DDH.
Swaddling hours: according to the 24-hour diaries of swaddling and non-swaddling patterns of mothers and research assistants' compliance check reports
Swaddling days: according to the 24-hour diaries of swaddling and non-swaddling patterns of mothers and research assistants' compliance check reports

3.5. Statistical analysis

Data will be double computerized using EpiData (The EpiData Association Odense, Denmark) and analyzed using Stata software 9 (Stata Corporation). All ultrasound examination pictures will be uploaded to the HipScreen platform.

Balance checks for the "swaddling" and "non-swaddling" groups will be conducted and reported for all key individual-level variables measured at baseline, including age at hip ultrasound screening in days, gender, risk factors (birth weight ≥4000gr, breech delivery, family DDH history, parity etc.), Graf hip type, alpha angles at baseline and management.

The primary and secondary outcomes will be described as percentage adjusted for the available baseline variables.Outcomes will be evaluated in an intent-to-treat analysis. Univariate analyses will assess factors that will be associated with outcomes and identify potential confounders (with rate ratios of ≥2) or variables that differed between study groups at enrollment. These covariates will be included in multivariate analyses. Multivariate logistic regression will be used to estimate the adjusted risks for prevalent outcomes. Pearson's correlation coefficient will be calculated between "non-Type 1" and swaddling days and swaddling hours per day.

4. DURATION OF PROJECT

Data collection will start since September 2019 to March 2021. Another 3 months for data management and analysis and another 3 months for report writing are required. Therefore the total duration of the project is 18-24 months. The writing and publication of scientific papers may continue after this.

5. MAIN PROBLEMS ANTICIPATED

No major problems are anticipated.

6. EXPECTED OUTCOMES AND DISSEMINATION OF THE FINDINGS

We hypothesize that the swaddling would be harmful to Graf Type 2a hips. The results will be published in national and international journals. Also a booklet with a summary of the research findings, including the recommendations, will be produced and distributed to. To make our research findings known to the participating communities, the research team will disseminate the project results through Radio/TV programmes.

7. ETHICAL CONSIDERATIONS

The study protocol will be reviewed and approved by the Institutional Review Board at the National Center for Maternal and Child Health and the Ethical Review Committee of Ministry of Health, Mongolia prior to start the study. All research data collected will be stored securely and confidentially. Strict standards of confidentiality will be observed throughout the study scheduling, administration and disposition. 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 ID number. All paper, examination and 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.

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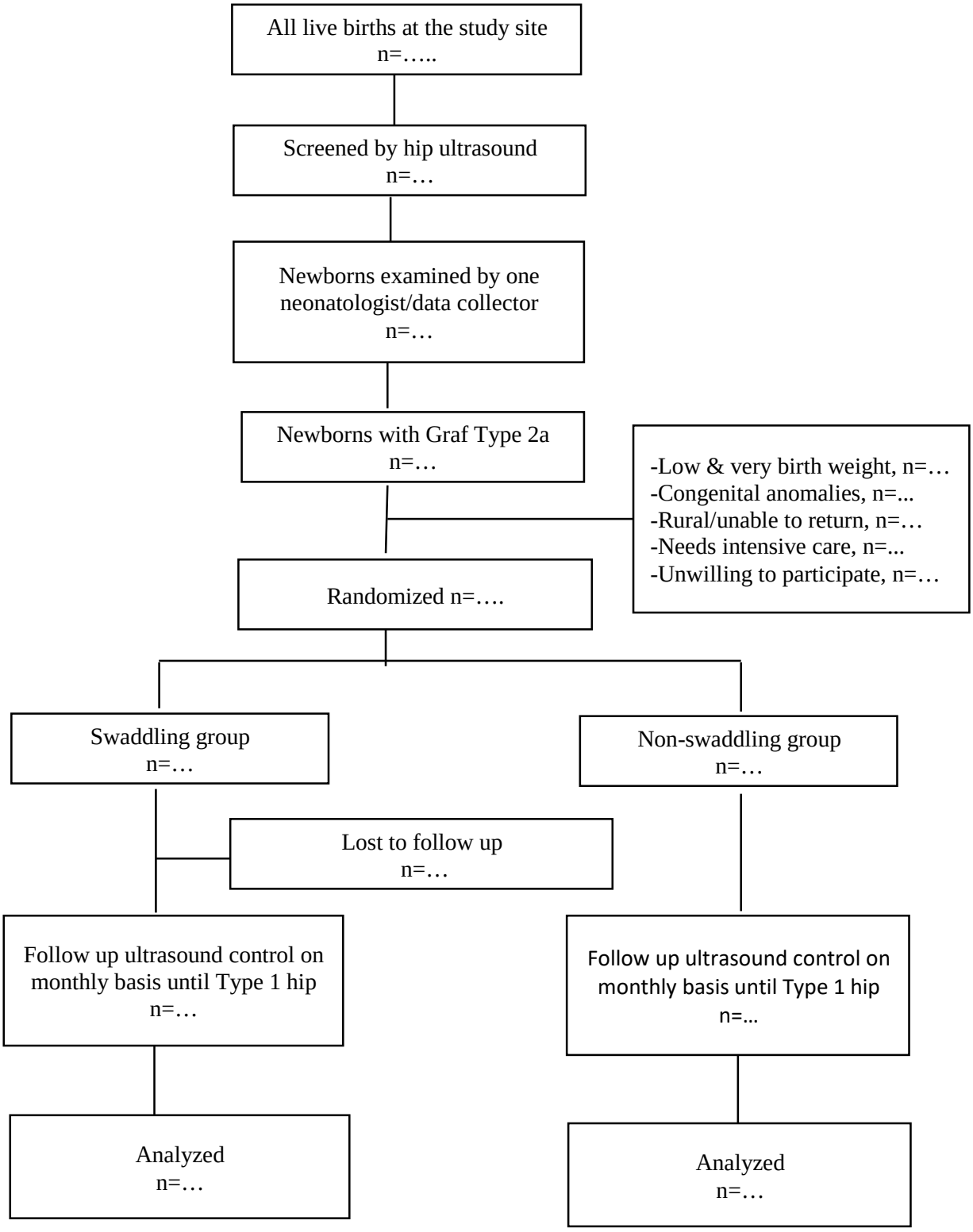
Annex 3. Trail profile reporting



Trail profile scheme

Annex 4. Data analysis plan

Table 1. Baseline characteristics of participants

Characteristics	Non-swaddling N= n(%)	Swaddling N= n(%)	P value*
Mean age in days at screening (mean ±sd)			
Girls			
Breech position			
Family history of DDH			
Birth weight >4000			
Firstborn baby			
Mean of Graf hip alpha angle at initial screening (mean ±sd)			
Swaddling days			
Swaddling hours per day in			

sd-indicates standard deviation, DDH indicates Developmental Dysplasia of the Hip

**chi2 or χ^2 test*

Table 2. The associations between the main outcomes and the intervention analyzed by univariate analysis (chi2 or χ^2 test)

Characteristics	Control n/N (%)	Intervention n/N (%)	OR	P value
Mean age in days at screening				
Girls				
Breech position				
Family history of DDH				
Birth weight >4000				
Firstborn baby				
Mean of Graf hip alpha angle at initial screening				
None-Type 1 hips				
DDH				
Rim defects at follow-ups				

Table 3. The associations between the main outcomes and the intervention analyzed by multiple logistic model

	Control n/N (%)	**Intervention n/N (%)**	**Adjusted OR***	**P**
Primary outcome				
None-Type 1				
Secondary outcome				
DDH				
Rim defect				

DDH indicates Developmental dysplasia of the hip, OR indicates odds ratio

**Will be adjusted for significant baseline variables*