ISRCTN11228572 https://doi.org/10.1186/ISRCTN11228572

Swaddling and problems with the way a baby's hip joint forms

Submission date
04/11/2020

Recruitment status
No longer recruiting

Registration date
10/11/2020

Overall study status
Completed

Last Edited
10/03/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Developmental dysplasia of the hip (DDH) is a problem with the way a baby's hip joint forms. Sometimes the condition starts before the baby is born, and sometimes it happens after birth, as the child grows. It can affect one hip or both. DDH is a major health problem that can lead to lifelong disability if the diagnosis is missed in the first weeks of life. Mongolia is the first Asian country that launched a universal ultrasound hip screening for DDH in newborns. All DDH cases are followed up on monthly basis by hip ultrasound and treated with a simple splint if necessary. In the country, swaddling is an ancient practice and nowadays it still remains common child care in the first months of life. The 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 ties. This practice requires a tight wrapping with stretched legs and the hips are held in an adducted position, which may play a role in the development of DDH. This hypothesis is going to be tested in this study.

Who can participate?
All newborns with physiologically immature hip

What does the study involve?
The term newborns with Graf Type 2a hip (physiologically immature) are randomly allocated to one of two groups. The intervention/non-swaddling group are instructed not to swaddle at all. The control/swaddling group are swaddled in the common traditional Mongolian method. Both groups are followed up by Graf’s method of hip ultrasound at 4-6 week intervals until healing according to Mongolian national guideline. All infants in need of therapy (Graf type 2a-, 2c or worse) are treated with a Tubingen splint. At around 12 months of age, all children are re-checked by Graf’s method of hip ultrasound.

What are the possible benefits and risks of participating?
There are no risks for the participants. All babies will be examined and controlled until healing by an experienced pediatricians’ team regularly for free.

Where is the study run from?
National Center for Maternal Child Health (Mongolia)

When is the study starting and how long is it expected to run for?
March 2018 to March 2022

Who is funding the study?
Swiss-Mongolian Pediatric Project (SMOPP)

Who is the main contact?
Dr Munkhtulga Ulziibat, umunhtulga@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Munkhtulga Ulziibat

ORCID ID
http://orcid.org/0000-0001-6549-9082

Contact details
Research Institute
National Center for Maternal and Child Health
Khuvisgalchdyn Street
Bayangol District
Ulaanbaatar
Mongolia
16060
+976-9917 5523
umunhtulga@gmail.com

Type(s)
Scientific

Contact name
Dr Munkhtulga Ulziibat

Contact details
Research Institute
National Center for Maternal and Child Health
Khuvisgalchdyn Street
Bayangol District
Ulaanbaatar
Mongolia
16060
+976-9917 5523
umunhtulga@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
05/SMOPP

Study information

Scientific Title
Traditional Mongolian swaddling and developmental dysplasia of the hip: a randomized controlled trial

Study objectives
Mongolian traditional prolonged swaddling where arms and legs are extended and hips are in adduction position increases the risk for DDH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 29/01/2019, Institutional Review Board at the National Center for Maternal and Child Health (Khuvisgalchdyn Street, Bayangol District, Ulaanbaatar, 16060, Mongolia; +976-11-362886; baylag.m@gmail.com), ref: 04/2019
2. Approved 26/01/2019, Ethical Review Committee of Ministry of Health, Mongolia (Ulaanbaatar city 14210, Sukhbaatar District, Olympic Street 2, Governmental building VIII, Mongolia; +976-11-263695; moh@moh.gov.mn), ref: 133/2019

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional file ISRCTN11228572_PIS (added 02/12/2020)

Health condition(s) or problem(s) studied
Developmental dysplasia of the hip

Interventions
The “swaddling” group are swaddled in the common traditional Mongolian technique while the “non-swaddling” group are instructed not to swaddle at all.

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 group have to be provided with alternatives to the readily available swaddling clothes and blankets, the control group are given a blanket and several cotton sheets at the time of recruitment. All enrollees are followed up on monthly basis for 12 months until healing (Graf Type 1) by hip ultrasound and treated with an extension and abduction Tubingen splint if necessary.

Randomization: On the first days after birth, all eligible newborns are screened using Graf’s method of ultrasound according to Mongolian National Guideline. After the screening all newborns, a list of all newborns with Graf Type 2a hips are generated on a daily basis. All term newborns with Graf Type 2a cases (physiologically immature) of the data collector /neonatologist are eligible for the study.
Randomization sequence is 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 the consent obtaining, details of the allocated group are given on colored cards contained in sequentially numbered and sealed envelopes. These are prepared by the principal investigator and kept in an agreed location on the post-delivery ward. Randomization takes place before discharge when the data collector/neonatologist gives detailed consultation on usual postnatal care of newborns. Corresponding envelopes are opened 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 are aware of the allocated arm, the outcome assessor/radiologist are kept blinded to the allocation.

Intervention Type
Other

Primary outcome measure
Graf’s alpha angle measured by ultrasound at baseline, 4-6 weeks, 8-10 weeks, 12-14 weeks, 16-18 weeks, 50-54 weeks

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
21/03/2018

Completion date
25/03/2022

Eligibility

Key inclusion criteria
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 complaints

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
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) weight

Date of first enrolment
02/08/2019

Date of final enrolment
25/03/2021

Locations

Countries of recruitment
Mongolia

Study participating centre
National Center for Maternal and Child Health
Khuvisgalchdyn Street
Bayangol District
Ulaanbaatar
Mongolia
16060

Sponsor information

Organisation
National Center for Maternal and Child Health

Sponsor details
Khuvisgalchdyn Street
Bayangol District
Ulaanbaatar
Mongolia
16060
+976-11-362 886
ehemut_mongolia@yahoo.com

Sponsor type
Government

Website
http://www.ehemut.mn

ROR
https://ror.org/05d2zbe90

Funder(s)

Funder type
Government

Funder Name
Swiss Mongolian Pediatric Project (SMOPP)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Will individual participant data be available (including data dictionaries)? yes
What data in particular will be shared? All of the individual participant data collected during the trial, after deidentification

What other documents will be available? Study Protocol
When will data be available (start and end dates)? End of recruitment and Immediately following publication.
With whom? Researchers who provide a methodologically sound proposal.
For what types of analyses? To achieve aims in the approved proposal
By what mechanism will data be made available? Proposals should be directed to umunhtulga@yahoo.com. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (www.ehemut.mn)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	29/06/2019	02/12/2020	No	Yes
Protocol file			02/12/2020	No	No
Results article		13/10/2021	10/03/2022	Yes	No