ISRCTN17899692 https://doi.org/10.1186/ISRCTN17899692

Comparison of electric breast pump and inverted syringe technique to see the effect on breastfeeding in lactating women with nipple inversion

Submission date
12/08/2024

Recruitment status
No longer recruiting

Registration date
13/08/2024

Overall study status
Completed

Last Edited
11/09/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Breastfeeding is ideal nutrition for all newborns. However, the success of breastfeeding often depends on a lot of factors, one of which is proper attachment to the mother's breast. Mothers with inverted or flat nipples often face a lot of difficulties in breastfeeding their newborns. An inverted nipple is a common developmental anomaly, with an estimated prevalence of 10%. The inverted syringe is the least expensive technique to correct inverted nipples, however, this method is also painful. Breast pumps are electronic devices that are used for expression of breast milk. Breast pump suction is very similar to the sucking and feeding of healthy infants. As the breast pump mimics the suckling pattern of the newborn, it can also cause eversion and elongation of inverted nipples. It is hypothesized that the usage of an electric breast pump is a less painful and more effective way of establishing breastfeeding in these mothers. This study aims to compare the success of breastfeeding with the help of the inverted syringe technique versus the success of breastfeeding with the help of an electric breast pump in mothers with inverted or flat nipples. The study will also look at the scale of pain expressed by a mother while using a breast pump versus pain expressed by a mother while using a syringe.

Who can participate?
Women with inverted or flat nipples of term neonates born at All India Institute of Medical Sciences Patna

What does the study involve?
This is an open-labelled randomly allocated and controlled trial that will be conducted by the Department of Neonatology at AIIMS PATNA. Participants will be allocated into two groups 1:1 using a computer. Group A will be instructed to use a cut disposable 10ml syringe to evert their nipples before each feed. After that mothers are instructed to latch the baby on the breast and feed for 10-20 minutes on either breast. Group B will be instructed to use the Madela Symphony electric breast pump for hospital use, on each breast for 15-20 minutes before each feed. After that mothers are instructed to latch the baby on the breast and feed for 10-20 minutes on either

breast. This procedure will be done after each feed and for a total of 3 days or after the achievement of successful lactation with an everted nipple, whichever is earlier. The rate of successful latching and attachment with satisfactory breastfeeding will be checked on day 3 of the postnatal period. Using a visual analog pain scale, mothers will be asked to document the degree of pain felt with syringing and while using the breast pump. This recording will be done once a day and the maximum amount of pain experienced during syringing will be compared in both groups.

What are the possible benefits and risks of participating?
This study was done to help understand which mode of intervention, inverted syringe or breast pump is more successful in establishing breastfeeding in lactating mothers with inverted nipples, with the least amount of pain.

Where is the study run from?
All India Institute of Medical Sciences Patna, India

When is the study starting and how long is it expected to run for?
September 2022 to September 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Bhabesh Kant Chowdhary (Principal Investigator), drbhabeshkc@aiimspatna.org
Dr Richie Dalai (Scientific and public contact), dr.richie11713@aiimspatna.org or richie.aiims@gmail.com

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AIIMS/Pat/IEC/2022/956

Study information

Scientific Title
Breastfeeding success with use of electric breast pump versus inverted syringe technique in lactating women with inverted or flat nipple: Open Labelled Randomized Control Trial

Study objectives
Electric breast pump suction provides a more physiological correction of the inverted nipple in lactating mothers compared to the syringing technique which leads to better breastfeeding rates with less nipple pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/10/2022, IEC AIIMS Patna (Institute Ethics Committee All India Institute of Medical Sciences Patna) (Phulwari Sharif, Patna, 801507, India; +916122821105; researchdivision@aiimspatna.org), ref: AIIMS/Pat/IEC/2022/956

Study design
Single-center interventional parallel-group open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Exclusive breastfeeding in lactating mothers with inverted nipples

Interventions
This study is a single-center, Interventional, parallel-group, open-label randomized controlled trial with allocation concealment performed using sequentially numbered opaque sealed envelopes and randomization computer-generated with variable block sizes with a 1:1 allocation ratio.

Participants were lactating mothers with inverted nipples in whom two different methods (Syringing vs. Electric Breast Pump) were tried to achieve eversion and establishment of exclusive breastfeeding by day 3 of the postnatal period.

The participants were randomized into 2 parallel intervention groups (Group A and Group B) in a 1:1 ratio. Mothers allocated to Group A were instructed to use a cut disposable 10 mL syringe to evert their nipple before each feed. Mothers were shown how to place the cut syringe over their nipple and gently pull till the nipple was everted, maintaining it for one minute, after which the syringe was removed and breastfeeding started. They were asked to feed for a minimum duration of 20 minutes.

Mothers allocated to Group B were instructed to apply the Madela Symphony electric breast pump (which was made available in their respective post-natal ward) to their breasts for 15 minutes or longer if eversion was not yet achieved. Following this they were instructed to latch the baby on breast and feed for at least 20 minutes.

Intervention Type
Device

Pharmaceutical study type(s)
Two devices (cut syringe vs. electric breast pump) were used to look at efficacy of establishment of breastfeeding by day 3

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electric breast pump, inverted syringe

Primary outcome measure
Establishment of direct breastfeeding by day 3 postpartum period without the need for continued intervention to evert the nipple measured using a categorical variable (Yes/No) by day 3 postnatal period

Secondary outcome measures
Pain in the nipple experienced by the mother after using the assigned intervention measured using a Visual Analog Scale (VAS) on days 1, 2, and 3 of the postnatal period

Overall study start date
01/09/2022

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Lactating mothers with inverted nipples of term neonates born at All India Institute of Medical Sciences Patna with APGAR >7 at birth.

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Breast cancer or on cytotoxic/chemotherapy drugs
2. Requiring admission to the intensive care unit (ICU) within 24 hours of delivery
3. Mothers of neonates requiring NICU admission within 24 hours of birth
4. Mothers of neonates who have oro-pharyngeal abnormalities like cleft lip/palate

Date of first enrolment
15/10/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences Patna (AIIMS Patna)
Phulwari Sharif
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801507

Sponsor information

Organisation
All India Institute of Medical Sciences Patna (Aiims Patna)

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Sponsor type
Hospital/treatment centre

Website
https://aiimspatna.edu.in/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Dr Bhabesh Kant Chowdhary, drbhabeshkc@aiimspatna.org.

The type of data available is in .dta format (STATA). These data will be available once the study is published in a peer-reviewed journal. Consent from participants was required and obtained. Data will be in a de-identified format, after removing names, and registration numbers. There are no ethical restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			11/09/2024	No	No
Results article		29/08/2024	11/09/2024	Yes	No