

Can gentle pressing of the chest of newborns delivered by Caesarean section simulate the squeezing of fluid from the baby's lungs during vaginal delivery and improve the baby's breathing in the hours after birth?

Submission date 03/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/03/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This is a new maneuver designed to improve the respiratory outcome of the newborns delivered by caesarian section. The idea is simple; the researcher suggests a maneuver through artificial compression of the chest of newborns delivered by caesarian section to simulate the squeezing effect of the normal vaginal delivery in order to evacuate the lung fluid as much as possible.

Who can participate?

Term and near term babies (> 35 weeks gestational age)

What does the study involve?

This is a new maneuver designed to improve the respiratory outcome of the newborns delivered by caesarian section. It involves artificial compression of the chest of newborns delivered by caesarian section to simulate the squeezing effect of the normal vaginal delivery in order to evacuate the lung fluid as much as possible. The maneuver will be trialled on term and near term babies (> 35 weeks gestational age) from the three participating centres throughout the study period.

What are the possible benefits and risks of participating?

The technique of this maneuver is important that it should be done with repetitive gentle compression of both sides of the chest; too little compression is of no benefit; whereas too much compression may cause fracture of the ribs and cardiac arrhythmias.

Where is the study run from?

1. Al-Batool Teaching Hospital, Mosul
2. Al-Khansa teaching hospital, Mosul
3. Nineveh private hospital, Mosul

When is the study starting and how long is it expected to run for?
February 2018 to December 2018

Who is funding the study?
Nenavah health office, Mosul, Iraq

Who is the main contact?
Dr Mohammed Hamid Al-sabawi
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A new maneuver for initial resuscitation of newborns after Caesarean delivery

Study objectives

This study is designed to improve the respiratory outcome of the newborn delivered by caesarean section and to decrease the incidence and duration of transient tachypnea among these newborns due to wet lung syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

interventional case-control study

Primary study design

Interventional

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available.

Health condition(s) or problem(s) studied

Transient tachypnea of newborns

Interventions

The researcher suggests a maneuver through gentle artificial compression of the chest of newborns delivered by caesarian section to simulate the squeezing effect of the normal vaginal delivery in order to evacuate the lung fluid as much as possible. This "Mohammed's maneuver" is done by upside-down position of the baby then gentle compression on the lateral sides of the chest of newborn for several times either by one or both hands of the obstetrician while the assistant is carrying the newborn or by carrying of the newborn by one hand of the obstetrician and compression of the chest by the other hand. It is preferably accompanied by suction of fluid from nose and mouth of newborn. This maneuver is safe and should not takes >30 seconds. The pressure of compression should be neither be too little or too severe.

Intervention Type

Procedure/Surgery

Primary outcome measure

Respiratory outcome of the newborns delivered by caesarian section measured using APGAR score assessed at 1, 5, 10, 15, and 20 min after birth.

Secondary outcome measures

The length of time the newborn displays transient tachypnea following birth.

Overall study start date

01/01/2010

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Term and near term babies (> 35 weeks gestational age)

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

500

Key exclusion criteria

1. Preterm (< 35 weeks gestation) neonates

Date of first enrolment

01/02/2010

Date of final enrolment

10/12/2018

Locations

Countries of recruitment

Iraq

Study participating centre

Al-Batool Teaching Hospital (Gynaecology And Obstetrics)

Nenaveh

Mosul

Iraq

14004

Study participating centre
Al-Khansa teaching hospital
Nenaveh
Mosul
Iraq
14004

Study participating centre
Nineveh private hospital
Nenaveh
Mosul
Iraq
14004

Sponsor information

Organisation

Nineveh Health Directorate Training Center & Human Development

Sponsor details

Nineveh
Mosul
Iraq
41001
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mslhrtdc@gmail.com

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Nenavah health office

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed neonatal journal.

Intention to publish date

10/03/2019

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 and will be included in the subsequent results publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/12/2019	12/12/2019	No	No
Results article		11/11/2020	23/03/2023	Yes	No