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Early manual rotation (EMR)

Submission date
05/02/2016

Recruitment status
No longer recruiting

Registration date
03/03/2016

Overall study status
Completed

Last Edited
25/06/2021

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
When a mother is giving birth, if the baby is looking upward instead of downwards in the womb it is harder for the baby to be delivered. The mother is known to have to push longer, and there is an increased chance that the mother will have to have help delivering her baby with, for example, a c-section , forceps or vacuum delivery. There is also an increased chance that she will have severe tears to her vagina. Rotating the baby's head by the hand of the physician is one way to turn the baby to the easier "looking down" position. This study looks whether trying to rotate the baby at the beginning of the pushing stage of labor would make for an easier delivery for the baby and mother. Specifically, the study investigates how long it takes the mother to push the baby out (in what is called the second stage of labor), the risk of severe tears to the vagina, and the likelihood of whether a c-section, forceps or vacuum delivery is necessary when comparing one group of mothers that were allowed to start pushing without rotating the baby, and another where rotation was tried at the start of pushing.

Who can participate?
Mothers (aged at least 18) giving birth for the first time with babies that are full term.

What does the study involve?
Participants are randomly allocated to one of two groups. For those in group 1, rotation of the baby is attempted before they are allowed to start pushing. Those in group 2 are allowed to start pushing before the baby is rotated. All participants are assessed see how long the second stage of labor takes, type of delivery they undergo (was it vaginal or c-section for example), and whether the mothers suffer from any severe tearing of the vagina.

What are the possible benefits and risks of participating?
Benefits of the study includes a reduction in how long the second stage of labor takes and an easier delivery of the child. Possible risks include injury to the baby's head from the rotation, or risk of the umbilical cord coming down in front of the baby's head during the rotation which would require an urgent c/section. Prior studies have showed that these complications are very rare.

Where is the study run from?
Utah Valley Regional Medical Center (USA)

When is the study starting and how long is it expected to run for?
June 2009 to September 2012

Who is funding the study?
Investigator initiated and funded (USA)

Who is the main contact?
Dr Jeff Broberg
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
RMS# 1014958

Study information

Scientific Title
A randomized controlled trial of prophylactic early manual rotation of the occiput posterior fetus at the beginning of the second stage vs. expectant management

Acronym
EMR

Study objectives
Rotation of the fetal head at the beginning of the second stage of labor in nulliparous women will decrease the time of maternal pushing, as compared to women who pushed without rotation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Prolonged second stage of labor

Interventions
Nulliparous women at term having their first vaginal delivery were randomized to either:
1. Attempted early manual rotation of the fetus or
2. Expectant management
The expectant management group could be rotated later in the second stage for other indications (arrest of descent or for other maternal or fetal indications)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Length of the second stage of labor - measured in minutes from the time pushing was initiated until delivery of the baby, as documented in the delivery record by labor and delivery nursing staff.

Key secondary outcome(s))
1. Operative delivery - delivery method recorded as spontaneous vaginal delivery, operative vaginal delivery (forceps or vacuum), or cesarean delivery.
2. 3rd or 4th degree laceration rate - recorded as on the delivery record as assessed by the delivery physician at the time of delivery.

All assessed at the time of delivery, recorded by the delivering doctor at the time provider is filling out the delivery record.

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. At least18 years old
2. Having first vaginal delivery
3. Term gestation (more than 37 weeks gestation)
4. Must have reassuring fetal status and maternal status

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
65

Key exclusion criteria
1. Preterm
2. Non reassuring fetal or maternal status
3. Multiparous

Date of first enrolment
01/01/2010

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
United States of America

Study participating centre
Utah Valley Regional Medical Center (Intermountain Health Care)
United States of America
84604

Sponsor information

Organisation
Utah Valley Regional Medical Center

ROR

https://ror.org/019n8y489

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	25/06/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes