

Early manual rotation (EMR)

Submission date 05/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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
Dr Jeff Broberg

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/06/2009

Completion date

30/09/2012

Eligibility

Key inclusion criteria

1. At least 18 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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

60

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

Sponsor details

1034 N 500 W

Provo, Utah

United States of America

84604

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/019n8y489>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Paper has been recently presented as an oral presentation at the Society of Maternal Fetal Medicine Conference in Atlanta, Georgia, February 2016. Paper is being prepared to be submitted to the American Journal of Obstetrics and Gynecology.

Intention to publish date

01/06/2016

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