ISRCTN11794106 https://doi.org/10.1186/ISRCTN11794106

Should we restrict food intake during labor?

Submission date
30/10/2023

Recruitment status
No longer recruiting

Registration date
02/12/2023

Overall study status
Completed

Last Edited
20/11/2024

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
The practice of telling women not to eat during labor, as advised by anesthesiologists and obstetricians, isn't necessarily backed by strong scientific evidence. Most caesarean deliveries nowadays use regional anesthesia rather than general anesthesia, which means there might not be a strong medical reason to restrict food intake during labor. Plus, it might not align with what the patients prefer.
Given the current landscape of more flexible obstetric and midwifery care, we think it's time to reconsider the old rule that banned eating during labor. It's important to carefully select patients who are at low risk and have a discussion with them about the pros and cons. The aim of this study is to find out whether patients should decide for themselves whether they want to eat during labor.

Who can participate?
Pregnant women at full term (at least 37 weeks into pregnancy) in the second phase of labor.

What does the study involve?
All patients were during labor under epidural anaesthesia. The standard medical treatment was given without any changes. All patients were allowed to consume water or clear fluids. Patients who were randomly allocated for oral food intake (Food group) were allowed to eat during labor. Food intake was not limited to specific foods, but the researchers recommended avoiding greasy food and suggested a diet of light food such as energy bars, fruit or yogurt. They asked the food intake group to consume food at least every 2 hours but did not force it.

What are the possible benefits and risks of participating?
The regular protocol during labor is fasting for food and allowing water or clear fluids, Participants in the control group followed the unit protocol. The study group was allowed to eat with the benefit of autonomy, avoiding hunger which can lead to stress, anxiety and impatience. The risk of eating during labor is the urge to vomit if there is pain and the risk for aspiration, both were eliminated by recruiting only patients under epidural anaesthesia and no pain.

Where is the study run from?
Meir Medical Center (Israel)

When is the study starting and how long is it expected to run for?
December 2018 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Gil Shechter Maor, gil.shechter@clalit.org.il

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Gil Shechter Maor

ORCID ID
http://orcid.org/0000-0002-8526-2143

Contact details
Meir Medical center
Kfar saba
Israel
4428164
+972 97472210
gil.shechter@clalit.org.il

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0258-17-MMC

Study information

Scientific Title
Should we restrict food intake during labor? A randomized controlled trial

Study objectives
Eating during labor will not affect its progression and outcomes. We aim to evaluate maternal complications related to food intake during labor, such as aspiration and chemical pneumonitis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/11/2018, Meir Medical Center Review Board (Meir Medical Center, Kfar Saba, 4428164, Israel; +972 97471588; meirhelsinki@clalit.org.il), ref: 0258-17-MMC

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Food intake during labor

Interventions
All patients were allowed to consume water or clear fluids before entering the labor room and having epidural anesthesia. After signing an informed consent, patients were randomized for oral food intake (food group) or clear liquids only (fluid group). Randomization was done using an online tool (https://www.Random.org, list randomizer). Food intake was not limited to specific foods, but the researchers recommended avoiding greasy food and suggested a diet of light food such as energy bars, fruit or yogurt. The researchers asked the food intake group to consume food at least every 2 hours but did not force it. The analysis was done based on intention to treat and the quantity of food consumed was not measured, to simulate the situation of individual labor processes and the free will to choose what to eat. The fluid group were allowed water, juice with no pulp (apple juice for example) and tea without milk.

Intervention Type
Behavioural

Primary outcome measure
A composite outcome of complications attributed to eating during labor and delivery. The researchers included emergent cesarean section, assisted vaginal deliveries and other indications for interventions that might need a general anesthesia with a potential risk of aspiration and chemical pneumonia such as uterine revision or manual lysis of retained placenta and advanced vaginal lacerations, general anesthesia, postpartum fever, aspiration and prolonged postpartum hospitalization of 5 days and more attributed to complications of aspiration measured using patient records at the end of the study.

Secondary outcome measures
Oxytocin augmentation during labor, second stage duration, need for analgesia, emergent cesarean section, early maternal and neonatal outcomes, aspiration and chemical requirements measured using patient records at the end of the study.

Overall study start date
18/12/2018

Completion date
03/12/2020

Eligibility

Key inclusion criteria
Singleton, term gestation (≥37 weeks) during the end of the latent phase of the early second phase of labor, based on regular painful contractions and cervical examination. To decrease the risk of general anesthesia, which is a known risk factor for aspiration, the researchers recruited patients after receipt of epidural anesthesia.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
116

Total final enrolment
129

Key exclusion criteria
1. Women with pregestational or gestational diabetes
2. Multiple gestations
3. Non-reassuring fetal heart rate prior to randomization

Date of first enrolment
18/12/2018

Date of final enrolment

09/06/2020

Locations

Countries of recruitment
Israel

Study participating centre
Meir Medical Center
Tchernichovskyy st 59
Kfar Saba
Israel
4428164

Sponsor information

Organisation
Meir Medical Center

Sponsor details
Tchernichovsky st 59
Kfar Saba
Israel
4428164
+972 (0)97472561
Michal.kovo@clalit.org.il

Sponsor type
Hospital/treatment centre

Website
http://www.clalit-global.co.il/en/meyer_medical_center.html

ROR
https://ror.org/04pc7j325

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during or analysed during the current study are available upon request from Dr Gil Shechter Maor (gilshec@gmail.com). A table of raw non-identified coded data is available until approval. Consent from participants for using the data anonymously was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/11/2024	20/11/2024	Yes	No