

Should we restrict food intake during labor?

Submission date 30/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/11/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

45 years

Sex

Female

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

ROR
<https://ror.org/04pc7j325>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes