ISRCTN14847686 https://doi.org/10.1186/ISRCTN14847686

Is six hours fasting time enough in term pregnancy? An ultrasound study of the stomach of fasted pregnant patients who are ≥36 weeks pregnant to determine if the 6 hours fasting time before an operation is enough in pregnancy

Submission date
26/08/2016

Recruitment status
No longer recruiting

Registration date
13/09/2016

Overall study status
Completed

Last Edited
15/09/2016

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fasting (not eating or drinking) before surgery is essential if a patient is going to receive a general anaesthetic (be put to sleep) for surgery. This is because when a person is anaesthetised, the body's natural reflexes stop. If the stomach has food or drink in it, there is a risk that it may be brought up and inhaled into the lungs (aspiration), which can affect breathing as well as cause damage to the lungs. As a rule, patients need to fast for a minimum of six hours after having a light meal (e.g. tea and toast), for two hours after having clear fluids, and for eight hours after a full meal. Pregnant women have a higher risk of aspiration because of the various changes that happen to the body during pregnancy. The aim of this study is to find out whether six hours fasting time is enough for heavily pregnant women to have an empty stomach.

Who can participate?
Adult women who are at least 36 weeks pregnant with a single baby.

What does the study involve?
Participants receive a phone call a day or two before their first antenatal (pregnancy) visit after 36 weeks at the hospital advising them not to eat or drink anything for 6 hours after having a light meal before the appointment. At the appointment, participants have their stomach scanned with an ultrasound probe in order to see how much is in their stomach. After the scan, participants are allowed to eat and drink as normal.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involves with participating in this study.

Where is the study run from?
The National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
August 2016 to December 2016

Who is funding the study?
The National Maternity Hospital (Ireland)

Who is the main contact?
Dr Sheeba Hakak
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EC 22-2016

Study information

Scientific Title
Is six hours' fasting time enough in term pregnancy ? A prospective observational cohort study using ultrasound to determine the residual gastric volume in fasted pregnant patients of ≥36 weeks gestation

Study objectives

The aim of the study is to determine whether six hours fasting time is enough in term pregnancy by performing ultrasound of the stomach after six hours of fasting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HSE Research Ethics Committee (National Maternity Hospital, Dublin), 06/09/2016.

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Anaesthesia during pregnancy

Interventions
Participating patients are contacted lead investigator a day or two before their regular antenatal appointment and given instructions what time to start their fast, and what to eat just before starting fasting (i.e. tea and toast). They will also be informed the location of the scan.

On the day of the appointment, the lead investigator will meet the patients and confirm the fasting times and carry out a gastric ultrasound in the supine position first followed by right lateral decubitus position (RLD) at their antenatal appointment after having fasted for six hours.

Patients charts will be reviewed by the lead investigator to obtain the necessary information like weight, height, and BMI.

Intervention Type
Procedure/Surgery

Primary outcome measure
Percentage of patients who have a critical residual gastric volume after six hours of fasting is determined
by assessing gastric volumes in ml/kg using gastric ultrasound at the study visit.

Secondary outcome measures

No secondary outcome measures

Overall study start date
01/08/2016

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Singleton pregnancy with a gestational age of 36 weeks or above
3. Ability to understand study protocol and provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
75

Key exclusion criteria
1. Patient refusal to participate
2. Comorbidities affecting gastrointestinal motility, such as diabetes or preecclampsia
3. Previous gastric surgeries,hiatus hernia
4. BMI >35
5. Oligo or polyhydramnios on most recent scan
6. Severe intrauterine growth retardation

Date of first enrolment
15/09/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Ireland

Study participating centre
The National Maternity Hospital
2 Holles street
Dublin
Ireland
Dublin 2

Sponsor information

Organisation
The National Maternity Hospital

Sponsor details
2 Hollis Street
Dublin
Ireland
Dublin 2

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The National Maternity Hospital

Results and Publications

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

Intention to publish date
30/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	12/09/2016	15/09/2016	No	Yes