

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	☒ Prospectively registered ☐ Protocol
Registration date 13/09/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/09/2016	Condition category Pregnancy and Childbirth	☐ 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 involved 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

Protocol serial number
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.

Primary study design

Observational

Study design

Prospective observational cohort study

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Patient refusal to participate
2. Comorbidities affecting gastrointestinal motility, such as diabetes or preeclampsia
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

ROR

<https://ror.org/03jcx214>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The National Maternity Hospital

Results and Publications

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