

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

<b>Submission date</b> 26/08/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/09/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
shakak@nmh.ie

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Sheeba Hakak

**Contact details**  
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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  $\geq 36$  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 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

**Sponsor details**  
2 Hollis Street  
Dublin  
Ireland  
Dublin 2

**Sponsor type**  
Hospital/treatment centre

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

## **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?
<a href="#">Participant information sheet</a>	version V2	12/09/2016	15/09/2016	No	Yes