

# Influence of forearm fractures on gastric emptying

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<b>Registration date</b> 12/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/09/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Aspiration of gastric content is the entry of stomach contents into the lungs. It is a major complication during surgery with anaesthesia. Therefore before surgery it is important to know that the patient has fasted. It seems common knowledge that only a fasted patient can undergo elective surgery. Under normal circumstances a patient is considered fasted 6 hours after their last solid meal and 2 hours after the intake of clear fluids. A non-fasted patient has an increased anaesthetic risk. Trauma (injury) is believed to delay gastric (stomach) emptying and negatively affects fasting status. However, this assumption is not supported by broad evidence. It seems plausible that minor trauma (i.e. a forearm fracture) affects gastric emptying to a lesser degree than major trauma. The aim of this study is to find out whether a minor trauma (forearm fracture) can delay gastric emptying.

### Who can participate?

Patients aged 18 and over with a forearm fracture that needs surgical repair

### What does the study involve?

Gastric emptying is assessed by ultrasound scans of the upper left abdomen at admission and before surgery.

### What are the possible benefits and risks of participating?

The possible benefit for the participants is a verified fasting status before surgery. This is beneficial for the anaesthetic management. The risks of an abdominal ultrasound scan are almost negligible.

### Where is the study run from?

AUVA-Unfallkrankenhaus Wien Lorenz Böhler (Austria)

### When is the study starting and how long is it expected to run for?

May 2017 to October 2023

### Who is funding the study?

AUVA Institute for Traumatology Research (Austria)

Who is the main contact?

1. Dr Daniel Lahner
2. Prof. Gerhard Fritsch

## Contact information

### Type(s)

Scientific

### Contact name

Dr Daniel Lahner

### Contact details

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### Type(s)

Scientific

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Prof Gerhard Fritsch

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## Additional identifiers

### Protocol serial number

EK-29-2017

## Study information

### Scientific Title

Does a forearm fracture delay gastric emptying assessed by ultrasound? A prospective observational study in adult trauma patients

### Study objectives

Null hypothesis: A forearm fracture does not delay gastric emptying.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics committee of AUVA hospitals, 05/07/2017, ref: EK-29-2017

**Study design**

Prospective observational single cohort study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Preoperative gastric emptying

**Interventions**

The aim of this study is to test preoperative gastric emptying in patients with a fractured forearm. Gastric content will be assessed by an abdominal ultrasound examination at admission and before surgery. The total duration of the observation will be the time span between admission and eligibility for surgery (approx. 6-8 hours) with no additional follow up planned.

**Intervention Type**

Other

**Primary outcome(s)**

Gastric emptying, determined by measuring gastric content with an abdominal ultrasound examination at admission (baseline, timepoint 1) and at eligibility for surgery (timepoint 2)

**Key secondary outcome(s)**

1. Pain, measured using the visual analogue scale (VAS)
2. Medication/relevant co-morbidities, retrieved from medical history
3. Factors influencing the quality of the ultrasound examination, determined posthoc

**Completion date**

31/10/2023

**Eligibility****Key inclusion criteria**

1. Adult patients suffering from a forearm fracture that deems postponed urgent surgical fixation
2. Age 18+ years; no maximum age is specified in the protocol

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pregnant patients
2. Patients with fractures that need urgent surgical intervention
3. Patients suffering from fractures in multiple locations

**Date of first enrolment**

01/09/2017

**Date of final enrolment**

01/09/2023

**Locations**

**Countries of recruitment**

Austria

**Study participating centre**

**AUVA Traumazentrum Wien**

Donaueschingenstraße 13

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**Study participating centre**

**AUVA Trauma Centre Salzburg**

Dr.-Franz-Rehrl-Platz 5

Salzburg

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**Sponsor information**

**Organisation**

AUVA Traumazentrum Wien

**Organisation**

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

AUVA Institute for Traumatology Research

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from the investigator (Dr Daniel Lahner). Available data: Individual participant data that underlie the results, after deidentification (text, tables, figures, and appendices). The data will be available beginning 3 months and ending 3 years following article publication to researchers who provide a methodologically sound proposal for data meta-analysis. Proposals should be directed to Dr Daniel Lahner. To gain access, data requestors will need to sign a data access agreement. Data will be made available via a secure encrypted file transfer service. Patient data is anonymised by consecutive numbering. The informed consent obtained from the participants includes approval of data sharing after deidentification.

### **IPD sharing plan summary**

Available on request