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Influence of forearm fractures on gastric emptying

Submission date	Recruitment status	[ ] Prospectively registered
21/08/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/09/2021	Surgery	[ ] 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
Donaueschingenstraße 13
Vienna
Austria
1200

Type(s)
Scientific

Contact name
Prof Gerhard Fritsch

Contact details
Donaueschingenstraße 13
Vienna
Austria
1200

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/05/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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
Vienna
Austria
1200

Study participating centre
AUVA Trauma Centre Salzburg
Dr.-Franz-Rehrl-Platz 5
Salzburg
Austria
5010

Sponsor information

Organisation
AUVA Traumazentrum Wien

Sponsor details
Donaueschingenstraße 13
Vienna
Austria
1200

Sponsor type
Hospital/treatment centre

Website
www.ukhlorenzboehler.at/

Organisation
Ludwig Boltzmann Institute for Experimental and Clinical Traumatology

Sponsor details
Donaueschingenstraße 13
Vienna
Austria
1200

Sponsor type
Research organisation

Website
http://trauma.lbg.ac.at/

Funder(s)

Funder type
Research organisation

Funder Name
AUVA Institute for Traumatology Research

Results and Publications

Publication and dissemination plan
1. The study protocol is available upon request from Dr Daniel Lahner or from the local ethics committee (ethikkommission@auva.at) under the reference number EK-29-2017.
2. Dissemination of the study results by publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2023

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