

Determination of the fluid volumes in the gastrointestinal tract of older adults

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| Submission date 13/02/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/02/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 22/01/2025 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Gastrointestinal (GI) fluids are fluids that are present in the stomach, small intestine, and large intestine. The volume of GI fluids is determined by fluid secretion and absorption by the GI organs and the intake of food and drink. While taking drugs, GI fluids can influence the solubility and absorption of the drugs. Previously, it has been shown that the volumes of gastrointestinal fluids can be important for the absorption of especially poorly soluble compounds. To understand and predict the solubility and ultimately the exposure of compounds, it is valuable to know the effect of GI fluids. However, in the older population, this information is lacking. Up until now, to the best of the researchers' knowledge, only fluid volumes in the stomach, a part of the small intestine and a part of the large intestine in older adults have been studied. Hence, studies informing the fluids in the gastrointestinal tract as a whole in older adults are necessary. These are particularly important to correctly predict the exposure of poorly soluble compounds. Magnetic resonance imaging (MRI) is a validated imaging approach that has already previously been used to quantify the GI fluid volumes in paediatrics and healthy adults. In this study, MRI will be used to measure the volume of GI fluid in older adults in the fasted state.

Who can participate?

Patients aged over 60 years who have undergone clinical MRI imaging at the University Hospitals Leuven in the past 10 years

What does the study involve?

This study will be conducted in collaboration with the Department of Radiology of the University Hospitals Leuven. Clinical MRI images are readily available of older adults who underwent clinical MRI imaging over the last decade. All images of older adult patients (age 60+ years) who received an abdominal MRI between 01/01/2012 and 31/12/2022 are of interest and will be evaluated. Images will be analysed using a viewer for medical image analysis and with an integrated software tool to calculate the fluid volumes in the stomach, small intestine and large intestine.

What are the possible benefits and risks of participating?

The main benefit of this study is the information gathered after evaluating the MRI images will result in knowledge about the fluid volumes in the stomach, small intestine, and large intestine.

With this knowledge, predictions can be made for the behaviour of newly developed compounds in the GI tract and ultimately their exposure in the older adult population. No risks are involved in this study for the participants, as their images will be retrospectively used.

Where is the study run from?

University Hospitals Leuven (Belgium)

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

January 2023 to December 2023

Who is funding the study?

Horizon 2020 programme of the European Union which is part of the Marie Skłodowska-Curie grant agreement No. 956146 AGePOP

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

S67554

Study information

Scientific Title

Quantification of fluid volumes in the gastrointestinal tract of older adults using magnetic resonance imaging (MRI)

Study objectives

Fluid volumes in older adults differ from young healthy adults

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Retrospective data study using clinical MRI data

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Physiological characterization of older adults

Interventions

This study will be conducted in collaboration with the Department of Radiology of the University Hospitals Leuven. Clinical MRI images are readily available of older adults who underwent clinical MRI imaging over the last decade. All images of older adult patients (age 60+ years) who received an abdominal MRI between 01/01/2012 and 31/12/2022 are of interest and will be evaluated. Images will be analysed using a viewer for medical image analysis (HOROS®, Horos project) and with an integrated software tool to calculate fluid volumes in the stomach, small intestine and large intestine.

Intervention Type

Other

Primary outcome measure

The total amount of fluid volumes present over the gastrointestinal tract in the fasted state in older adults, extracted from the MRI images taking into account the surface area of the fluid pocket, the slice thickness of the MRI imaging and the inter-slice gap between the images, measured at a single timepoint for each patient

Secondary outcome measures

More detailed quantification of the gastrointestinal fluid volumes with differentiation between the duodenum, jejunum, and ileum (if sufficient fluid is present, fluid volumes in the caecum and colon will also be quantified), measured using MRI images at a single timepoint for each patient

Overall study start date

30/01/2023

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. All abdominal MRI data generated in the past ten years (01/01/2012 and 31/12/2022)
2. Data generated in the University Hospitals Leuven (no other affiliated hospitals)
3. Older adults (age 60+ years)
4. All sexes

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

1800

Total final enrolment

100

Key exclusion criteria

1. Patients with gastrointestinal diseases or pathologies in their history
2. Post-mortem imaging
3. MR enterography examinations
4. Recent food or fluid intake based on stomach characteristics

Date of first enrolment

01/01/2012

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

Belgium

Study participating centre

UZ Leuven

Herestraat 49

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Belgium

3000

Sponsor information

Organisation

Universitair Ziekenhuis Leuven

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.uzleuven.be/en>

ROR

<https://ror.org/0424bsv16>

Funder(s)

Funder type

Government

Funder Name

Agepop - European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 956146

Results and Publications

Publication and dissemination plan

Publication in a high-impact peer-reviewed journal anticipated

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the medical characteristics of the generated data.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 05/12/2024 | 22/01/2025 | Yes | No |