Validation of the UC-IUS score

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Study Ongoing

Administrative details

EU PAS number

EUPAS107322

Study ID

199001

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

Rationale: Intestinal ultrasound (IUS) is a non-invasive, rapid, efficient and cost-efficient imaging technique, which has been proven to be accurate in assessing disease activity, severity and location in ulcerative colitis (UC) patients. To this date, the Milan Ultrasound score (MUC) is the only validated ultrasound index

for UC and differentiates between endoscopic Mayo (eMayo) 0-1 and 2-3. The STRIDE-II study suggests an eMayo score of 0 as treatment target for endoscopic remission, which underlines the need for a more sensitive IUS index. Recently, Bots et al. proposed a point-based index (UC-IUS score) corresponding with endoscopic disease severity, making it suitable for detecting an eMayo of both 0 and 1. External validation of this index remains to be investigated in an independent cohort of prospectively followed UC patients, which this study aims to provide. Objective: The primary objective of this study is to determine the accuracy of the UC-IUS index in determining presence of endoscopic disease activity in the sigmoid by using the eMayo score as gold standard. Secondary objectives include determination of cut-off values for eMayo 0-1 vs 2-3 and response, assessing sensitivity to change after treatment and establish inter- and intra-rater agreement. Exploratory objectives include the use of the UC-IUS index as a surrogate marker for long-term complications, assess if there is a difference in UC-IUS index cut-off for individual colonic segments, compare the accuracy of complete BWT or submucosal layer alone against the eMayo score, compare the UC-IUS score to the UCEIS and to compare the accuracy of the UC-IUS to the MUC and IBUS-SAS score.

Study status

Ongoing

Research institutions and networks

Institutions

Amsterdam UMC

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Primary lead investigator

Christoph Teichert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2023

Study start date

Planned: 01/12/2023

Actual: 09/11/2023

Date of interim report, if expected

Planned: 01/06/2025

Date of final study report

Planned: 01/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the study is to determine the accuracy of the UC-IUS index in determining the presence of endoscopic disease activity in the sigmoid by using the eMayo score as gold standard.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

A minimum of 64 patients, consisting of 32 eMayo 0 and 32 eMayo 1 patients.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

64

Study design details

Outcomes

The UC-IUS score to define mild endoscopic disease activity (defined as eMayo of 1) evaluated against patients with endoscopic remission (defined as eMayo score of 0), To determine: - the accuracy of the UC-IUS score to distinguish no to mild endoscopic disease activity versus moderate to severe endoscopic disease activity - the accuracy of decrease in UC-IUS score to distinguish endoscopic response versus no endoscopic response between baseline and follow-up (between week 12 & 26) after medical treatment of known efficacy - inter-and intra-rater variability

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Data analysis plan

The endoscopy and intestinal ultrasound are part of standard care, resulting in no extra burden for the patient. Preferably, patients will undergo the ultrasound when already in the hospital (e.g. for an infusion of medication, when admitted or when visiting the outpatient clinic). If this is not possible, an appointment for performing the ultrasound will be scheduled. IUS is a rapid and non-invasive imaging technique and having a reliable and standardized US activity index can be useful for facilitating the clinical decision-making process and for assessing and monitoring treatment outcomes in daily practice and in clinical trials.

Data management

ENCePP Seal

Conflicts of interest of investigators

COI_EUPAS107322.pdf(201.02 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No