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Health related Quality of Life and medication adherence in adult patients with autoimmune hepatitis, primary biliary cholangitis, primary sclerosing cholangitis and variant syndromes: a multicentre study

(Extension to: Health related Quality of Life and medication adherence in adult patients with autoimmune hepatitis: a multicentre, cross-sectional study.)

Background/aims:

Compare HRQoL of patients with PBC, PSC, Variant Syndromes and AIH. Identify disease specific factors that determine HRQoL.

Study design/Methods or/PROMS:

Longitudinal study (baseline, 2-year-FU, 5-year FU), paper-pencil-survey, Castor database
PROMS: General questions, SF-12v2 (QoL), EQ-5D-5L (QoL), GAD-7 (anxiety), PHQ-9 (depression), MFIS (fatigue), SSS-8 (somatic symptoms severity), SSD-12 (psychological reaction), BMQ (beliefs about medicine), VAS (adherence), MLQ (meaning in life), PBC-40 (disease specific QoL measure), SIBDQ (disease specific QoL measure)

Target population:

Adult patients with a diagnosis of PBC (n=800-1000), PSC (n=800-1000) and variant syndromes (n=150-200)

Languages:

Dutch, German, Hungarian, Polish, Italian, Portuguese, English, Danish (further translations possible)

Countries:

Radboudumc (The Netherlands), Universitätsklinikum Hamburg-Eppendorf (Germany), University of Debrecen (Hungary), Hannover Medical School (Germany); waiting for ethics vote: Medical University of Warsaw (Poland), Maastricht UMC+ (The Netherlands), Centro Hospitalar e Universitário de Coimbra (Portugal), University of Milano-Bicocca (Italy), Saarland University Medical Center (Germany)

Inclusion and exclusion criteria:

Inclusion:

- 18 years and older
- Diagnosis of PBC, diagnosis of PSC, diagnosis of a variant syndrome

Exclusion:

- Liver transplantation
- Hepatocellular Carcinoma
- Inability to read and understand the language of study documents

Study period/begin/stage:

Recruitment period: 01/01/2022 – 31/12/2022

Open for inclusions: yes

Contact details:

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