RESULTS

Participant flow

Altered values of liver test ALT and / or AF were detected in 802 patients admitted to IPS Universitaria between 03/11/2015 and 03/11/2016. The number of excluded patients was 516. In total, 286 met the inclusion criteria, the informed consent was signed, the necessary information was extracted for each patient, and the cause of the alteration in liver enzymes was identified.

Baseline characteristics

The mean age was 58.0 (SD 19.4), of whom 164 patients (57.3%) were female.

Outcome measures

Liver test and associated drugs on the admission to the study

ASSOCIATED DRUG	ALT (U/L)	AST (U/L)	ALP (U/L)
Isoniazid (300mg, 24h, oral)	2125 1266	2221 1961	194 282
Phenytoin (100 mg, 12h, oral)	28	30	614
Valproic acid (250 mg, 24h, oral)	788	945	164
Isoniazid 75mg + Rifampicin 150mg + Pyrazinamide 400mg + Ethambutol 275mg (4 tablets, 24h, oral) (3 tablets, 24h, oral)	200 413 394	351 289 148	148 114 139
Albendazole (200mg, 12h, oral)	182	123	616
Acetylsalicylic acid (100mg, 12h, oral)	306	298	177
Trimethoprim 80mg-sulfamethoxazole 400mg (12h, oral)	734	227	562
Rifampicin (150mg, 24h,oral)	261	147	89
Pregabalin (300mg, 8h, oral)	204	902	70
Diclofenac (75mg/3ml, 24h, intramuscular) and dexamethasone (4mg/1ml, 24h, intramuscular)	444	133	213
Meglumine antimonite (1500mg/5ml, 24h, intramuscular)	188	166	112
Metformin (850mg, 24h, oral)	346	376	97
Daptomycin (600mg, 48h, intravenous)	241	237	906
Nitrofurantoin (100mg, 6h, oral)	304	108	117
Senna and acacia (not avalilable)	482	369	186

The mean age was 58.0 (SD 19.4), of whom 164 patients (57.3%) were female. The risk factors associated with the cases of DILI were concomitant use of medications, such as methotrexate, atorvastatin, leflunomide, itraconazole, or metronidazole (88.9%); comorbidities, such as rheumatoid arthritis, heart failure, histoplasmosis, and liver abscess (33.3%); alcohol consumption not considered as alcoholism (16.7%); previous alcohol consumption (11.1%); and viral infections (11.1%). The nonspecific signs and symptoms presented by patients with DILI included cytopenia, hepatomegaly, jaundice, epigastric pain, vomiting, nausea, fever, choluria, asthenia, rash, eosinophilia >6%, right upper quadrant pain, pruritus, anorexia, acholia, or arthralgia (from higher frequency to lower). One patient was asymptomatic.

Adverse events

Incidence of hepatotoxicity by drugs approximately of 6%.