| Author, Year  Trial name  N | Were harms prespecified and defined? | Were ascertainment techniques for harms adequately described? | Were ascertainment techniques for harms equal, valid, and reliable? | Was duration of followup adequate for harms assessment? | Harms Quality Rating | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| Bailey,1974145  178 | Yes | Yes | Yes | No | Fair | Adherence to treatment and data points for followup unclear |
| Bush, 196543  All subjects: 2,238  ≥15 years: 1309  ≥20 years: 1140 | Yes | No | No | Yes | Poor | Low retention; thus, full extent of harms unavailable in data |
| Byrd, 1977146  120 | Round 1:  Yes  Round 2:  Partially | Round 1: Partially, although unclear if INH patient data presenting SGOT values by symptoms were limited to Round 1 INH patients  Round 2: No; unclear if INH patient data presenting SGOT values by symptoms included Round 2 INH patients; data limited to those who had high SGOT levels and/or DC treatment | Round 1: Yes  Round 2: Partially | Round 1: Yes  Round 2: Partially | Fair | Patients only followed for 3 months of 3-month treatment; limited data presented from Round 2 |
| Falk, 197841,148  7,036 | No | No | No | Yes | Poor | No consistent method for obtaining information on harms  No followup labs or other formal process to adequately assess for elevated LFTs, hepatotoxicity, or other AEs  They surveyed the investigators to determine any known cause of toxicity (unclear, but seems to have been a post-hoc survey; and no further information about what the survey contained or how the investigators collected information to respond to the survey) |
| Ferebee, 196344  27,924 patients (566 psychiatric wards randomized); 25,210 patients included in morbidity analyses | No | No | NR | Yes | Poor | Only harm reported is number stopping pills because they were made “sick” from the pills |

**Abbreviations:** AE=adverse event; DC=discontinuation; INH=isoniazid; LFT=liver function test; SGOT=serum glutamic-oxalacetic transaminase.