

Supplementary Table 1. Summary of patient selection, inclusion criteria, and exclusion criteria for the three studies from which subjects were selected. For further details please see cited reference.

	Patient Selection	Inclusion Criteria	ExclusionCriteria
Database (24,25)	<ul style="list-style-type: none"> • Patients with suspected or histologically proven NAFLD • ≥ 2 years of age • Enrollment: 10/2004 -2/2008 • Subjects were followed until 9/2009. • 1,206 adults and 296 children • Liver biopsies obtained only when clinically indicated 	<p>Any one of the following criteria:</p> <ul style="list-style-type: none"> • Histologic diagnosis of NAFLD • Histologic diagnosis of cryptogenic cirrhosis • Suspected NAFLD based on imaging studies • Clinical evidence of cryptogenic cirrhosis. 	<ul style="list-style-type: none"> • Clinical or histological evidence of alcoholic liver disease • Alcohol consumption during the 2 years before entry of more than 20 g daily for men and 10 g daily for women. • Other forms of chronic liver disease • History of total parenteral nutrition, biliopancreatic diversion, bariatric surgery, Short bowel syndrome, suspected or confirmed hepatocellular carcinoma • Known positive for HIV • Conditions that were likely to interfere with study follow-up • Inability to provide informed consent.
PIVENS (26,27)	<ul style="list-style-type: none"> • ≥ 18 years of age • Enrolment: 1/2005 - 1/2007 • 247 adults (includes 162 patients subsequently enrolled in Database study at the completion of the trial) • Eligibility based on standard of care tests and procedures 	<p>Liver biopsy within 6 months before randomization showing either:</p> <ul style="list-style-type: none"> • NAS ≥ 5 with a minimum score of 1 for all three components plus possible or definite steatohepatitis • NAS=4 with a minimum score of 1 for all three components plus a finding of definite steatohepatitis 	<ul style="list-style-type: none"> • Exclusion as Database Study above plus: • Medications suspected of having an effect on NASH in the 3 months before the biopsy, • History of diabetes mellitus or heart failure • Evidence of cirrhosis • Use of drugs historically associated with NAFLD or known hepatotoxins
TONIC (28,29)	<ul style="list-style-type: none"> • 8 - 17 years of age at entry • Enrollment 9/2005 – 9/2007 • 173 children (includes 78 patients subsequently enrolled in Database study at the completion of the trial) • Eligibility based on standard of care tests and procedures 	<ul style="list-style-type: none"> • Serum ALT elevation (> 60 U/L) on two occasions more than 30 days but less than one year apart • Liver biopsy indicating NAFLD obtained within 6 months before randomization (defined as a minimum of 5% of hepatocytes with macrovesicular fat, without other etiologies) 	<ul style="list-style-type: none"> • Exclusion as Database Study above plus: • Medications suspected of having an effect on NASH in the 3 months before the biopsy, • History of diabetes mellitus • Evidence of cirrhosis • Normal ALT • Lack of liver biopsy within the designated time • Use of drugs historically associated with causing NAFLD or known hepatotoxins