

Evaluating *Oxalobacter formigenes* as at treatment for Primary Hyperoxaluria

The effectiveness and safety of *Oxalobacter formigenes* treatment in patients with Primary Hyperoxaluria (PH), will be evaluated in a research trial, expected to start late 2009 to early 2010 in the USA, Germany and Netherlands.

Oxalobacter formigenes is a unique oxalate degrading bacteria naturally present in the intestine of 50-70% of the general population. This bacterium uses only oxalate as its energy source and therefore it efficiently degrades oxalate. When *Oxalobacter formigenes* is taken the oxalate degrading bacteria are released into the intestine where they continuously degrade oxalate. This excessive break down of oxalate in the intestine may help dissolve the extra oxalate being produced by the liver in patients with PH. If the bacterium can do this, less oxalate will be filtered through the kidneys into the urine.

Participants in this study will receive *Oxalobacter formigenes* or a placebo. The duration of the study is approximately 6 months and the study medication is given orally twice a day. Eligibility for this study will be determined at the study center. If you or your child has PH and are at least 2 years old and interested in participating in this trial, please talk to your doctor.

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