



Registry of Hypogonadism in Men (RHYME)

Background

Study Objectives

The Registry of Hypogonadism in Men (RHYME) is a large, multi-national observational (non-intervention) registry for men with testosterone deficiency syndrome designed to confirm and extend available information on the safety of testosterone therapy.¹

RHYME is sponsored and conducted by the New England Research Institutes, Inc. (NERI), with the support of a research grant from Bayer Schering Pharma.

Study Design

An estimated 1000 hypogonadal men from 20 clinical research sites in Europe will participate in the registry for a minimum of two years. RHYME will also gather data to examine the natural history, progression, and current treatment options for the disease. In particular, it will examine the association between testosterone deficiency syndrome, testosterone therapy and prostate health outcomes in men with hypogonadism. It will also assess routinely-monitored symptoms/general health outcomes associated with testosterone therapy. Data will be collected using a combination of medical history, physical examination, blood tests and self-administered questionnaires.

Currently, more than 250 patients have been enrolled in Germany, Italy, the Netherlands, Spain, Sweden and the United Kingdom. Final study results are anticipated in 2013.

About Hypogonadism and Metabolic Syndrome

Studies suggest that hypogonadism in men (also known as testosterone deficiency syndrome) is often under-diagnosed and under-treated; because the symptoms can be easily attributed to aging or other medical causes. It is estimated that low testosterone affects 20% of all men over the age of 60.²

The effects of hypogonadism can have a very serious impact on quality of life and cause men to experience diminished sexual desire and erection quality/frequency, changes in mood and decreased cognitive function, decreased lean body mass and muscle volume/strength, increased visceral fat, and decreased bone and mineral density. Further, it has been shown that low testosterone can be associated with metabolic syndrome,³ a condition involving a cluster of risk factors for cardiovascular disease, including abdominal obesity, high blood pressure; high fasting blood glucose, high triglyceride and low HDL cholesterol levels. Around 20-25 percent of the world's adult populations present a metabolic syndrome and they are twice as likely to die from – and three times as likely to have – a heart attack or stroke than people without a metabolic syndrome.⁴ A report has identified a clear relationship between low testosterone levels in men and the metabolic syndrome.⁵ Researchers found that men with the metabolic syndrome were 2.8 to 3.2 times more likely to develop hypogonadism, as defined by total testosterone levels less than 11 nmol/L.⁶

About NERI

NERI is a clinical research organization dedicated to understanding diseases, functional processes and associated behaviors, and the effectiveness of treatment options. NERI has earned widespread recognition as a premier public health and social science research organization. Primary funding for IPASS is provided to NERI by Bayer Schering Pharma AG, which has a strong commitment to men's health.

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