

# Clinical trial protocol

**Title**

Efficacy and safety of a human normal immunoglobulin product for intravenous administration (IVIg) in the treatment of dermatomyositis (DM) and polymyositis (PM)

**Inclusion criteria:**

- Male or female patients of at least 18 years of age,
- Patients fulfilling the diagnostic criteria (definite or probable) of the European Neuro-Muscular Committee (ENMC) for idiopathic DM and PM.

**Exclusion criteria:**

- Pregnant women, nursing mothers and women of childbearing potential with no reliable contraception,
- Patients who do not fulfill the ENMC diagnostic criteria (definite or probable) of idiopathic DM and PM,
- Patients with a diagnosis of paraneoplastic DM or PM,
- Juvenile DM and PM (age less than 18 years).

**Start of the study:**

February 2006

**End of the study:**

August 2007

**Expected number of patients:**

44 patients (11 patients per subgroup: DM active, DM placebo, PM active, PM placebo)

**Trial phase:**

phase III

**Drug:**

human normal immunoglobulin product for intravenous administration (IVIg)

**Study design:**

The study will be randomized, double-blind, placebo-controlled

**National monocenter study**