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IMMUNOGLOBULIN AND IMMUNOMODULATORY THERAPY

EFFICACY, PHARMACOKINETICS AND SAFETY OF A NOVEL 10% INTRAVENOUS IMMUNOGLOBULIN (IVIg), IN PATIENTS WITH PID (PRIMARY IMMUNODEFICIENCY): A PROSPECTIVE MULTICENTRE STUDY

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Background:

In order to assess Tthe efficacy, pharmacokinetics and tolerability of I10, a novel IVIG, a prospective study was initiated in patients with PID

Methods:

A multicentre, open-label, prospective, single-arm study (Eudract 2010-023483-41) designed according to guidelines (Ref. 3). Approval was obtained from the respective national or institutional ethics committees (Ref. 2).

Primary endpoint:

Annualized number of serious bacterial infections (SBIs) per patient as defined in guidelines (Ref. 3), i.e. bacterial pneumonia, bacteraemia or sepsis, osteomyelitis, septic arthritis, visceral abscess and bacterial meningitis

Secondary endpoints:

· Efficacy: annualised rate of all infections and infection-related parameters (absence from school or work, hospitalisations, antibiotic treatment)

· Safety including vital signs and biological parameters

· Pharmacokinetics

Normal 0 21 false false false FR X-NONE AR-SA **Results:**