CVBF
Consorzio per Valutazioni Biologiche e Farmacologiche

Erasmus MC
University Medical Center Rotterdam
Erasmus

Paediatric European Network for Treatment of Pain

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GAPP

GAbapentin in Paediatric Pain

TOWARDS NEW THERAPIES TO CHALLENGE CHRONIC PAIN IN CHILDREN

COORDINATOR: CVBF - Consorzio per Valutazioni Biologiche e Farmacologiche

START DATE: July 1st 2013

DURATION: 48 months

CONSORTIUM: 15 partners

Chronic pain is estimated to affect 15-20% of children with underlying conditions, and is often poorly recognised and treated. To date, opioids, non-steroid anti-inflammatory drugs (NSAIDs), antidepressants and anticonvulsants are among the most commonly used medications to treat pain, but very few of these are formulated or authorised for paediatric use.

The GAPP project aims to improve the therapeutic prospects of children suffering from chronic pain with a neuropathic component, by developing a new paediatric formulation of gabapentin, a drug proven to be efficacious and safe in adults with neuropathic pain and in children with epilepsy. Gabapentin was included in the EMA-PDCO Priority List of off-patent medicines for which clinical development is strongly supported to respond to unmet medical needs.

The project brings together private and public research institutions and a patient representative (ICCCPO) from Albania, Estonia, France, Germany, Greece, Italy, the Netherlands, Spain and the United Kingdom. Together with the support of the European Commission, they will work to demonstrate that gabapentin, administered in personalised doses, is safe and efficacious for the treatment of children affected by chronic pain with a neuropathic component, both as monotherapy and, in the most severe cases, as add-on therapy to morphine. Within this project, a new oral liquid formulation will be developed to make the administration of gabapentin more precise and comfortable to young patients.

Objectives

The project's main goal is to demonstrate the efficacy and safety of gabapentin in children aged three months to 18 years suffering from chronic pain with a neuropathic component, using an age-appropriate liquid oral formulation developed as part of the research programme.

The Paediatric Investigation Plan (PIP) approved by the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) has the following objectives:

- to conduct a pre-clinical toxicity study (preGABA) aimed to verify the potential effects of high doses of gabapentin on the development of the mammalian central nervous system
- to collect pharmacokinetic data on gapapentin and identify optimal paediatric dosages for patients aged three months to 18 years
- to conduct two randomized, controlled clinical trials to evaluate the efficacy and safety of gabapentin in patients between 3 months and 18 years of age with moderate and severe chronic pain with a neuropathic component (GABA-1 and GABA-2, respectively)
- to conduct a bridging modelling study to extrapolate GABA-1 and GABA-2 results to children between 3 months and 3 years of age, addressing the paucity of data in this age group (GABA-3)

tel. +39 0809751974
www.pediatricpain.eu