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Clinical Trial Synopsis – Prematurely ended statement

EudraCT number	2007-001196-10
Trial identification	
Full title of the study	Effect of Cuprum Metallicum 15 CH on muscle cramps at dialysis, evaluation study in chronic hemodialyzed patients *(Etude d'évaluation de l'effet de Cuprum Metallicum 15 CH sur les crampes musculaires survenant en cours de dialyse chez des patients hémodialysés chroniques)*
Abbreviated title	CUPRUM METALLICUM
Sponsor protocol code	RC27022007
Investigational medicinal products (IMP identification)	Homeopathic medicinal product Cuprum Metallicum 15 CH
Sponsors	
Sponsor	BOIRON Laboratories
Sponsor Address	2 Avenue de l'Ouest Lyonnais 69510 Messimy FRANCE
Study Contact	Isabelle Chanel, Research & Development & Scientific & Medical Affairs Director BOIRON Laboratories isabelle.chanel@boiron.fr
Scientific Contact	Dr Abdellatif BENMOUSSA 85100-FR
Research Location and Sites	FR – 5 investigative sites
Member State Concerned	AFSSAPS (ANSM) - France
Results Information	
Actual start date of recruitment	06 DEC 2007
Global end of trial date	(*date of the end of participation of the last person included in the research*) 16 MAY 2008
Planned number of subjects to be included- Country	60 (France)
Number of subjects enrolled - Country	9 (France)
Clinical Trial Phase	III
Clinical Trial duration	5 months
Publication reference	none
General information about the trial	

Clinical Trial Type:	Therapeutic confirmatory
Design of the trial	Controlled – Randomized - Double blind - Parallel group – Comparator (Placebo)
Medical Condition	Hemodialysis-induced muscle cramps
Main objective of the trial	The main objective of the study was to evaluate the effect of Cuprum Metallicum 15 CH on the duration of the first cramp occurring at dialysis session.
Secondary's Objectives of the trial	The secondary objectives were to evaluate the effect of Cuprum Metallicum 15 CH on cramp intensity; the type of response to treatment after 3 and 6 minutes and the study treatment tolerance.
Principal Inclusion Criteria	Selection Criteria: - 18 to 85 years old, - Chronic hemodialyzed patient, *i.e.,* been undergoing 2 to 3 dialysis session a week for more than 6 months, presenting a stabilized renal pathology, - At least one history of cramp at dialysis session in the month preceding the selection visit. Inclusion Criteria: - Patient presenting an episode of cramp at the dialysis session. It is the onset of that cramp during the dialysis session that will determine the inclusion of a selected patient. See **Section E.3** for others
Principal Exclusion Criteria	Non-Selection Criteria: - Renal failure with non-stabilized renal pathology - Patient dialyzed since less than 6 months - Patient undergoing pains or muscle cramps generating pathology or any pathology considered by the investigator to interfere with evaluation criteria of the study. - Patient with a severe psychiatric pathology. - Pregnancy or breast feeding Non-inclusion criteria: patient having taken a muscle cramp onset reducing treatment 24 hours before the inclusion visit. See **Section E.3** for others
Trial Status:	Early Termination
Statistical Analysis Description	Statistical methods were presented in the protocol's statistical analysis session (version 12 – 18 June 2007). Not updated – Study cancelled

Summary – research Findings

BOIRON did not move forward with the Phase III (CUPRUM METALLICCUM in cramps of dialyzed patients).

Indeed, given a very low recruitment rate (3 active sites and 9 patients randomized over 6 months), the CUPRUM METALLICCUM project (EudraCT # 2007-001196-10) was **aborted in May 2008.**

As the study was underpowered due to limited enrollment and early termination, the inferential orientation of the original study objectives was no longer attainable. Due to the low number of subjects that completed, no descriptive statistics for the efficacy endpoints were provided. No inferential analysis comparisons were made.

Please consider this as a memo to file to close out this record.

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Name & Function Signature : Date of Transmission	Isabelle Chanel Director of Research & Development & Scientific & Medical Affairs. MAR 2023