

**Pulmonary Embolism International THrOmbolysis trial** 

## A reduced dose of thrombolytic treatment for patients with intermediate high-risk acute pulmonary embolism

EudraCT No.: 2018-000816-96; ClinicalTrials.gov Identifier: NCT04430569

Dear Investigators,

The « Assistance Publique-Hôpitaux de Paris (AP-HP) » and Aixial are happy to present to you the first PEITHO-3 Newsletter. The first of many to come for this important academic trial.

We already have some good news and successes to share with you!

# Public and institutional grants support PEITHO-3 in a growing number of participating countries

#### **France**

The study is being supported by a grant from the French Ministry of Health (PHRCN-16-0580).

#### Germany

PEITHO-3 is being supported by a grant from the German Research Foundation (*Deutsche Forschungsgemeinschaft*; KO 1939/3-1).

### **Belgium**

Our trial is also being supported by Life Sciences Research Partners (D Collen Research Foundation)

## **Spain**

The National Coordinator has obtained a grant from Spanish Ministry of Science and Innovation to support the trial in Spain. Congratulations to Dr. David JIMENEZ for this big achievement!

#### Canada

PEITHO-3 will cross the Atlantic; Dr. Kerstin de Wit has obtained a grant from the Canadian Institutes for Health Research (CIHR) to develop research in Canada. Congratulations to the Canadian team!

## **Protocol amendment**

The protocol is currently being amended and will be shared with you as soon as it is ready.



### Countries

- Austria
- Belgium
- France
- Germany
- Italy
- Netherlands
- Poland
- Portugal
- Romania
- Serbia
- Slovenia
- Spain
- Switzerland



92 Sites



650

## **Patients**



To assess the efficacy of reduced dose thrombolytic therapy in patients with intermediate high-risk acute pulmonary embolism

## **Regulatory submissions**

The study has been submitted to and approved by the French, German, and Austrian competent authorities. Aixial, is currently busy collecting site documentation and will start preparing the regulatory submissions for all other countries soon. Thank you in advance for your reactivity and cooperation with this task.

### Sub-contractors involved in this clinical trial

Four countries will be managed by the AP-HP; France, Germany and Austria (in cooperation with the Center for Thrombosis and Hemostasis Mainz), and Belgium (in cooperation with KU Leuven). For the other countries Aixial is the CRO in charge, but is working with several subcontractors. Please see an overview below of which company/subcontractor is involved for which country:

- AP-HP
- o Austria
- o Belgium
- o France
- o Germany
- Aixial
- o The
  - Netherlands
- Switzerland

- Experior
  - o Spain
  - o Portugal
  - o Poland
- Hungaro Trial
  - o Romania
  - o **Serbia**
  - o Slovenia
- Hippocrate
  - o Italy

## **Steering Committee**

The Steering Committee meeting which usually takes place during the ESC congress could not be held last year due to the current COVID-19 pandemic. We expect to organize one via teleconference at the end of May 2021. We will get back to you as soon as possible.

We would like to thank you for your patience during the start-up phase of this project.

Please do not hesitate to contact us if you need any further information and help.

Thank you again for your participation!

Best Regards,

Prof. Olivier SANCHEZ and Prof. Stavros KONSTANTINIDES

The AP-HP and Aixial teams



