

Unidad de Ensayos Clínicos**Agencia Española del Medicamento y Productos Sanitarios (AEMPS)**

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C. Campezo, 1
28922 Madrid

European Medicines Agency (EMA)

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject	EudraCT- Submission note
Protocol Study Title	Intraarterial Alteplase Versus Placebo After Mechanical Thrombectomy (CHOICE)
Article Study Title	Effect of Intra-arterial Alteplase vs Placebo Following Successful Thrombectomy on Functional Outcomes in Patients With Large Vessel Occlusion Acute Ischemic Stroke The CHOICE Randomized Clinical Trial
Protocol code	CHOICE
EudraCT Number	2018-002195-40
Product	Intra-arterial alteplase
Sponsor	Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	20th May 2021

13rd May 2026

To Whom It May Concern,

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS), hereby submit the attached article titled: "Effect of Intra-arterial Alteplase vs Placebo Following Successful Thrombectomy on Functional Outcomes in Patients With Large Vessel Occlusion Acute Ischemic Stroke The CHOICE Randomized Clinical Trial". Published online February 10, 2022 in JAMA, JAMA. doi:10.1001/jama.2022.1645, as the summary of results for the CHOICE Trial (EudraCT Number: 2018-002195-40).

This article contains all relevant information required by EudraCT, including:

- Study objectives and design
- Patient population and inclusion/exclusion criteria
- Treatment arms and interventions
- Primary and secondary outcomes

- Statistical analysis and results
- Safety data and adverse events
- Conclusions and clinical implications

The Sponsor confirms that the clinical trial CHOICE (EudraCT Number: 2018-002195-40) terminated early due to the inability to maintain placebo availability and slow enrolment related to the COVID-19 pandemic, after the inclusion and randomisation of 121 participants. As stated in the publication, only 60% of the planned sample size was reached.

In accordance with EudraCT guidance, results for prematurely terminated clinical trials may be submitted as a summary attachment when a full data set is not applicable or only partial results are available. The results of this study are therefore reported in aggregated form through the attached peer-reviewed publication. The attached article is a peer-reviewed publication that adequately reports the study design, methodology, results and safety outcomes, in line with the principles outlined in Annex I of the ICH E3 guideline.

The Sponsor confirms that it holds the rights to submit this document and that the attached publication accurately reflects the outcomes of the CHOICE clinical trial.

Please do not hesitate in contacting us should you need further information.

Sincerely,

Sara Campos
Application Submitter CTU CLINIC
FRCB – IDIBAPS