

BrainCool AB (publ): Ethical approval for the clinical study for stroke patients

The EU-funded multicenter randomized clinical trial, with a total study population of 400 stroke patients, has now received ethical approval.

The study participants are randomized into two groups, with 200 patients in each group. The intervention group will receive cooling treatment with BrainCool's products combined with thrombectomy and will be compared with a control group receiving the current standard treatment of today.

Stroke is the most common cause of disability in Europe with an estimated health cost of over EUR 45 billion, in 2020. This is a cost that is expected to rise by almost 44% until 2040, according to the European stroke organization Stroke Alliance For Europe (SAFE).

The primary endpoint and objective of the study, is to measure the proportion of survivors with good neurological function (mRS 0-2), with the aim of showing a statistically significant difference corresponding to an effective size difference of 14%, in terms of survival with good neurological function (defined as mRS 0 - 2).

Two interim analyzes are planned after 100 and 200 patients. The pre-specified cut-off value for ending the study earlier, requires a p-value of $p < 0.0025$.

CEO Martin Waleij comments:

"The clinical study is financed by an EU grant, [Ref 1](#); with the purpose of developing a new unique treatment for stroke patients. BrainCool runs an EU-funded project in collaboration with the University Hospital of Freiburg ("Freiburg"), establishing cooling therapy combined with thrombectomy. The goal is to significantly reduce stroke-related rehabilitation costs within Europe. The project has a timetable with the end set within the first quarter of 2025. By that time, the clinical study shall in other words be completed, and all regulatory applications for market approval of the new stroke treatment will have been submitted in both the EU and the USA."

References:

1 [MFN.se > BrainCool > BrainCool AB \(publ\): BrainCool satsar på att RhinoChill® System får central roll i behandlingen av stroke med trombektomi och att terapin godkänns som ny medicinsk indikation](#)

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About Us

BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. The company focuses on two business segments, Brain Cooling and Oncology. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Nasdaq First North Growth Market, named "BRAIN".
Eminova Fondkommission AB is the company's Certified Adviser.

Attachments

[BrainCool AB \(publ\): Ethical approval for the clinical study for stroke patients](#)