RAVIMIAMET

Axel Franz
Universitaetsklinikum Tuebingen AöR
Geissweg 3, Innenstadt
72076 Tübingen
GERMANY

16.09.2024 nr RKU-4/69

DECISION

to grant authorisation for clinical trial on the basis of Regulation (EU) No 536/2014 of the European Parliament and of the council

State Agency of Medicines has received the application from sponsor Universitaetsklinikum Tuebingen AöR on 06.08.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99^1 (1) of Estonian Medicinal Products Act (MPA).

Based on art 8 of Regulation (EU) No 536/2014, considering the aspects covered by Part I and Part II of the assessment report, on the basis of § 99^6 section 1 p 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no Albino under the following conditions:

protocol no: Albino (Version 7, dated May 22, 2023)

full title of the trial: Effect of ALlopurinol in addition to hypothermia for hypoxicischemic Brain Injury on Neurocognitive Outcome

sponsor of the trial: Universitaetsklinikum Tuebingen AöR

number of subjects in Estonia: 14

principal investigators and study locations:
- Dr Tuuli Metsvaht, Tartu University Hospital, Puusepa 1a, 50406 Tartu, Estonia
- Dr Pille Andresson, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia

The addressee may file a challenge with State Agency of Medicines within 30 days as of the day when the addressee became or should have become aware of the decision as prescribed in Code of Administrative Procedure § 71(1). If the addressee wishes to have the decision to annulled by the administrative court, he or she may submit a complaint to the Tartu Administrative Court as prescribed in § 7(1) and § 46(1) of the Code of Administrative Court Procedure within 30 days after the date on which the decision was notified to the applicant.

(digitally signed)

Katrin Kiisk
Director General