



RAVIMIAMET

Nicolette van Sluis
Stichting European Clinical Research Alliance
on Infectious Diseases
Archimedeslaan 6
3584 BA Utrecht
NETHERLANDS

28.11.2024 nr RKU-4/90

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 University Of Oxford on 11.09.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (2) and § 99¹ (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 § 99⁶ 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 RECOVERY under the following conditions:

protocol no: RECOVERY (Version 27.0, dated September 13, 2023)

full title of the trial: Randomised Evaluation of COVID-19 ThERapY

sponsor of the trial: University Of Oxford

number of subjects in Estonia: 120

starting date: November 2024

principal investigators and study locations:

- Dr Piret Mitt, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Maire Link, Sihtasutus Pärnu Haigla, Ristiku tn 1, 80010 Pärnu, Estonia
- Dr Dina Ambulte, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Mait Altmets, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 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