



RAVIMIAMET

Mikk Jürisson
University Of Tartu
Ravila tn 19
50411 Tartu
ESTONIA

19.12.2024 nr RKU-4/92

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 Tartu on 04.12.2024 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 EEPRS12308 under the following conditions:

protocol no: EEPRS12308 (Version 2.3, dated December 13, 2024)

full title of the trial: The Pragmatic EE-PRS Trial assessing Polygenic Risk Driven Statin Therapy for Cardiovascular Disease Prevention

sponsor of the trial: University Of Tartu

number of subjects in Estonia: 2500

starting date: December 2024

principal investigators and study locations:

- Dr Aet Elken, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Prof Margus Viigimaa, 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)

Ott Laius
Deputy Director General
on duties of Director General