InnovAATe
Inhaled AAT Clinical Study

Clinical study information for AATD patients

A Phase III, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Inhaled AAT for Alpha-1 Antitrypsin Deficiency | Study Identifier on ClinicalTrials.gov: NCT04204252

You may be eligible to participate in the study if:

- You are diagnosed with AAT Deficiency
- You have Z or Null mutations
- Your Age is 18-65
- You did not smoke in the past year

Study duration and clinic visits frequency

- 2 years of treatment with inhaled AAT or Placebo.
- 7 clinic visits during first year, 4 during second year
- 2 additional years of treatment with inhaled AAT will be offered
- At the end of treatment, there will be a 6- month follow-up period

Daily routine of the study

- Once daily inhalation of 80 mg AAT or Placebo, using PARI eFlow Nebulizer (approximately 15 minutes)
- eDiary daily filling, to monitor treatment and capture symptoms

Which tests are performed during clinic visits?

- Lung function tests (Spirometry, DLCO, lung volumes)
- Chest CT (once a year)
- 6-minute walking test
- Blood tests
- Quality of life questionnaire

Additional eligibility criteria and study tests will be detailed when you contact the study site

Important information

- Inhaled AAT is delivered directly to the lung using a dedicated nebulizer, at home.
- Travel cost to the study site is reimbursed according to country regulation
- Lost wages may be reimbursed according to country regulation

About KAMADA

A global biopharmaceutical company with a portfolio of 6 FDA-approved marketed products indicated for rare and serious conditions. Kamada is a leader in specialty plasma therapies focused on Alpha-1 Antitrypsin Deficiency. The company is advancing the InnovAATe study - a phase III pivotal study of inhaled AAT, aiming to develop the next-generation augmentation therapy.

To learn more about the study and to contact a study site visit www.innovaate-study.com, or scan the QR code

Study locations

KAMADA Ltd. 06/2023 | www.kamada.com | "Inhaled AAT" is an investigational product and is not approved for marketing
Kamada InnovAATe 008_Study intro sheet_v1_25Jun2023_English

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