

# Advair HFA in Healthy and HAPE Predisposed Subjects

NCT06040268

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1, Phase 2
<b>Sponsor</b>	University of Colorado, Denver
<b>Enrollment</b>	60 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Written informed consent signed prior to entry into the study.
- Male or female age 18-50 years of age
- BMI  $\geq 20$  and  $< 35$  kg/m<sup>2</sup>
- Agreement to comply with the study-required interventions and treatment during the full duration of the study.
- In good health as determined by screening medical history, physical examination, vital signs (blood pressure, heart rate, respiratory rate and temperature), clinical laboratory tests (CBC, prothrombin time (PT) (INR)/partial thromboplastin time (PTT), thyroid stimulating hormone (TSH), Total Bilirubin, blood chemistries, urine drug screening), and a resting 12-lead Electrocardiogram with a 10 second rhythm strip.

... and 4 more (see full listing online)

### Exclusion (36)

- Currently participating in or has been enrolled in another clinical trial within the last 30 days (observational studies are acceptable).
- Donation of any blood or plasma in the last month, or donation of  $> 500$  milliliters (ml) of blood within the 3 months preceding study drug administration.
- Female subjects of childbearing potential with positive serum pregnancy (beta human chorionic gonadotropin) test, who are breastfeeding, plan to become pregnant during the study, or decline to either be abstinent or use highly effective birth control if they have sexual intercourse with a male partner (ie, oral contraceptives; contraceptive patches, implants, injections, and rings; intrauterine devices - both hormonally-impregnated and untreated devices) throughout the study and for at least 1 month after study completion;
- Known history of impaired liver function
- Clinically significant laboratory abnormalities (one retest is allowed at the discretion of the Investigator and Medical Monitor), defined as:

... and 31 more (see full listing online)

## Locations (1 total)

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University of Colorado Anschutz Medical Campus, Aurora, Colorado, United States