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A phase 1, single-center, double-blind study of AM103 in healthy volunteers

Submission date	Recruitment status	[_] Prospectively registered
08/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2021	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-002229-59

Protocol serial number
The Sponsor (Amira) code: CL-AM103-01; PRA International (a contract research organization) code: AMA70921-070921

Study information

Scientific Title
A phase 1, single-center, double-blind study of AM103 in healthy volunteers

Study objectives
To assess the following:

Primary:
Safety and tolerability of single and multiple doses of AM103 following oral administration.

Secondary:
1. Pharmacokinetics (PK) of AM103 after single and multiple doses.
2. Effects of AM103 on Pharmacodynamic (PD) markers: whole blood ionophore-stimulated leukotriene LTB4 and urinary LTE4 production.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Review Committee (METC) of the BEBO foundation (Ethics Review / Bio-medical Research) (METC van de stichting BEBO) Postbus 1004, 9400 BA Assen, and Noorderstaete 20, 9402 XB Assen, the Netherlands. Approved on 22nd May 2007.

Primary study design
Interventional

Study design
Single-center, double-blind, randomized, placebo-controlled, single dose followed by multiple dose study.

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Healthy volunteers. Study is primarily relevant in asthma and allergic rhinitis.

Interventions
AM103 orally or placebo
Single doses: 50, 150, 300, 600, 1000 mg
Multiple doses: Administered once daily for 11 days. The doses are: 150, 300 and 600 mg, with an additional group to be defined (after the prior doses have concluded).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Adverse events
2. Physical examinations
3. Vital signs
4. ECGs
5. Clinical laboratory values

Single Dose Study: Physical examination, vital signs, ECG, and clinical laboratory tests will be carried out on Day 4 (72 ± 4 hours, end-of study time point) after study drug administration.

Multiple Dose Study:

Vital signs will be assessed at the following timepoints:
Day 1: pre-dose, 1, 2, 4, 12, and 24 hours after study drug administration
Days 2-10: pre-dose, 2 and 12 hours after study drug administration
Day 11: pre-dose, 2, 12 and 24 hours after study drug administration

Physical examination, vital signs, ECG, and clinical laboratory tests will be carried out on Day 14 (72 ± 4 hours after the Day 11 dose).

ECGs will be carried out at the following timepoints:
Single Dose Phase: 2-4 hours after the study drug administration
Multiple Dose Phase: 2-4 hours after the first dose of study drug on Day 1 and 2-4 hours after study drug administration on Days 5 and 11.

Key secondary outcome(s)
1. Pharmacokinetics: Concentrations of AM103 in plasma samples will be determined by validated Liquid Chromatography/Mass Spectrometry (LCMS) methods.
2. Pharmacodynamics: Whole blood ionophore-stimulated leukotriene LTB4 and urinary LTE4 production to be assayed by Enzyme Linked Immunosorbent Assay (ELISA) and mass spectrometry, respectively.

Completion date
31/10/2007

Eligibility

Key inclusion criteria
1. Male or female between 18 and 65 years of age (for Multiple Dose Phase, male only)
2. Female subjects must be postmenopausal, surgically sterile, or be prepared to use two methods of contraceptives during the study and for 14 days after the end of dosing
3. Non-smoker
4. Good general health as determined by medical history, and by results of physical examination, vital signs, Electrocardiogram (ECG), and clinical laboratory tests obtained within 21 days (3 weeks) prior to study drug administration
5. Able to provide written informed consent and understand and comply with the requirements of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Total final enrolment
86

Key exclusion criteria
1. Prior exposure to AM103 (no subject may participate in more than one cohort)
2. History or presence of any significant organ system disease, including phenylketonuria, as assessed by medical history, physical examination and laboratory evaluation
3. 12-lead ECG with any abnormality judged by the Investigator to be clinically significant or QTc interval of >450 milliseconds
4. Presence or history of any abnormality or illness, which in the opinion of the Investigator may affect absorption, distribution, metabolism or elimination of the study drug
5. Any screening laboratory evaluation outside the laboratory reference range that is judged by the Investigator to be clinically significant
6. Hemoglobin <7 mmol/L
7. Positive serum test for HIV, hepatitis C or hepatitis B virus infection
8. History of significant allergy to any medication
9. History of alcohol or drug abuse within the past 24 months or positive urine drug screen during screening
10. Use of any tobacco or nicotine containing product within the previous 6 months
11. Administration of any prescription drug within 21 days (oral contraceptives permitted) or over-the-counter drug (paracetamol and ibuprofen ≤1 g/day permitted) or herbal supplement within 7 days of study drug administration
12. Administration or use of any investigational drug or device within 30 days of study drug administration
13. Blood or plasma donation within 60 days prior to dosing

Date of first enrolment
18/06/2007

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Stationsweg 163
9470 AE Zuidlaren
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Sponsor information

Organisation
Amira Pharmaceuticals (USA)

ROR
https://ror.org/00gtmwv55

Funder(s)

Funder type
Industry

Funder Name
Amira Pharmaceuticals (USA)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/02/2010	29/10/2021	Yes	No