Randomized, double-blind, parallel group, Phase 2b dose-finding, efficacy and safety study of 12-week twice daily oral administration of BAY 1817080 compared to placebo in the treatment of refractory and/or unexplained chronic cough (RUCC)

Published: 25-02-2020
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Assess the efficacy of BAY1817080 as compared with placebo in terms of change in 24-hour cough count from baseline to week 12. Further assess the efficacy, safety and tolerability profile of BAY1817080 in patients with RCC

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON50167

Source
ToetsingOnline

Brief title
PAGANINI

Condition

- Bronchial disorders (excl neoplasms)

Synonym
refractory and/or unexplained chronic cough (RUCC)

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: Chronic Cough, P2X3 receptor antagonist, RUCC

Outcome measures

Primary outcome

Change from baseline in 24-hour cough count (measured by cough recording digital wearable monitoring device) after 12 weeks of intervention

Secondary outcome

1. Percentage of participants with a *30% reduction from baseline in 24-hour cough count after 12 weeks of intervention (measured by cough recording digital wearable monitoring device)

2. Change from baseline in 24-hour cough count after 2, 4, and 8 weeks of intervention (measured by cough recording digital wearable monitoring device)

3. Change from baseline in awake cough frequency per hour after 2, 4, 8 and 12 weeks of intervention (measured by cough recording digital wearable monitoring device)

4. Change from baseline in cough related quality of life (measured by Leicester Cough Questionnaire [LCQ]) after 12 weeks of intervention

5. Change from baseline in cough severity after 12 weeks of intervention (measured by Cough Severity Visual Analogue Scale [VAS])

6. Percentage of participants with a *30 scale units reduction from

baseline after 12 weeks of intervention (measured by cough Severity

VAS)

7. Percentage of participants with a *1.3-point increase from baseline

after 12 weeks of intervention (measured with LCQ Total Score)

8.Frequency and associated severity of treatment-emergent adverse events

(TEAEs)

Study description

Background summary

Researchers in this study want to find the optimal therapeutic dose of drug BAY1817080 for patients with long-standing cough with or without clear causes (refractory and/or unexplained chronic cough, RUCC). Study drug BAY1817080 is a new drug under development for the treatment of long-standing cough. It blocks proteins that are expressed by the airway sensory nerves which are oversensitive in patients with long-standing cough. This prevents the urge to cough. Researchers also want to learn the safety of the study drug and how well it works in reducing the cough frequency, severity and urge-to-cough.

Participants in this study will receive either the study drug or placebo (a placebo looks like the test drug but does not have any medicine in it) tablets twice daily for 12 weeks. Observation for each participant will last about 18 weeks in total. Participants will be asked to wear a digital device to record the cough and to complete questionnaires every day to document the symptoms. Blood samples will be collected from the participants to monitor the safety and measure the blood level of the study drug.

Study objective

Assess the efficacy of BAY1817080 as compared with placebo in terms of change in 24-hour cough count from baseline to week 12. Further assess the efficacy, safety and tolerability profile of BAY1817080 in patients with RCC

Study design

Randomized, double-blind, parallel group, Phase 2b dose-finding, efficacy and safety study of 12-week twice daily oral administration of BAY 1817080 compared to placebo in patients with RUCC.

Study duration: approximately 18 weeks
screenings period: approx. 2 weeks
intervention duration: 12 weeks
safety follow up period

Intervention

Experimental: BAY1817080
- 150 mg BID--Study drug BAY1817080 will be administered orally as tablet.
- 75 mg BID--Study drug BAY1817080 will be administered orally as tablet.
-25mg BID--Study drug BAY1817080 will be administered orally as tablet.
- Placebo comparator: placebo BID--Matching Placebo for BAY1817080 will be administered orally as tablet.

Each participant will be randomized to receive one of three oral doses of BAY 1817080 or placebo, administered twice daily over the course of 12 weeks.

Study burden and risks

NA

Contacts

Public
Bayer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adults * 18 years of age at the time of signing the informed consent.
2. A cough that has lasted for at least 12 months with persistently bothersome refractory (unresponsive to treatment options) or idiopathic (unexplained) chronic cough.
3. persistent cough for at least 8 weeks before screening.
4. Women of childbearing potential must agree to use acceptable effective or highly effective birth control methods during the study and for at least 30 days after the last dose.
5. Capable of giving signed informed consent.

Exclusion criteria

1. Smoking history within the last 12 months before screening (all forms of smoking, including e-cigarettes, cannabis and others), and any former smoker with more than 20 pack-years.
2. Ongoing or previous exposure to inhalational toxic fumes (e.g., ammonia, chlorine, nitrogen dioxide, phosgene and sulfur dioxide) within the last 12 months before screening.
3. Respiratory tract infection within 4 weeks before screening.
4. History of chronic bronchitis.
5.Systolic blood pressure * 160 mmHg and/or diastolic blood pressure * 100 mmHg at screening visit.
6. Positive SARS-CoV-2 virus RNA and/or serology IgG tests at screening visit.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2020
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	25-02-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-04-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-08-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-10-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-05-2021
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-05-2021
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-004169-42-NL
CCMO	NL72426.075.20