A PHASE I, SINGLE-CENTRE, RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED, SINGLE- AND MULTIPLE ASCENDING-DOSE STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF GRC 10693 IN HEALTHY MALE SUBJECTS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON33904

Source
ToetsingOnline

Brief title
A Phase I to study GRC 10693 in Healthy Male Subjects.

Condition

- Peripheral neuropathies

Synonym
Chronic neuralgia

Research involving
Human

Sponsors and support

Primary sponsor: Glenmark Pharmaceuticals SA.
Source(s) of monetary or material Support: Glenmark Pharmaceuticals SA.

Intervention

Keyword: GRC 10693, Multiple ascending dose, Pain, Single ascending dose

Outcome measures

Primary outcome

The study has three objectives. Firstly, we will study the safety and

tolerability of the drug after the administration of both single and multiple

doses of the drug.

Secondary outcome

Secondly, we will study the speed at which the drug is absorbed in the body, as

well as the degree of elimination of the drug after single and multiple doses.

Third, in the MAD part in this research also the pain-relieving effect of the

researchdrug is examined after administration of pain stimuli on the basis of

two pain models.

Study description

Background summary

GRC 10693 is a new drug that can stimulate the cannaboid-2-receptor. The cannaboid-2-receptor has an action in transmitting pain signals in patients with chronic neuralgia. Stimulation of the cannaboid-2-receptor could limit the transmission of these pain signals. GRC 10693 would be a pain killer for

patients with post herpatic neuralgia or neuralgia due to diabetes.

Study objective

The study has three objectives. Firstly, we will study the safety and tolerability of the drug after the administration of both single and multiple doses of the drug. Secondly, we will study the speed at which the drug is absorbed in the body, as well as the degree of elimination of the drug after single and multiple doses. Third, in the MAD part in this research also the pain-relieving effect of the researchdrug is examined after administration of pain stimuli on the basis of two pain models.

Study design

SAD: (At least) Seven groups of eight healthy male volunteers will participate in this study. The study will include a medical examination, one admission period of three days, visits on days 4 and day 5, and finally a follow-up.

MAD: Four groups of eight healthy male volunteers will participate in this study. The study will include a medical examination, one admission period of eighteen days, three short visits and finally a follow-up.

Study burden and risks

The risks for the volunteers participating in this trial are related to the possible side effects of the investigational product. Next, the inconvenience for the volunteer depends on the duration of the admission period, venapunctures and inserting the cannula. All volunteers will be closely monitored by experienced physicians and other staff.

Contacts

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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. Subjects must be Caucasian males, 18-45 years of age, inclusive;
2. Subjects must voluntarily sign a written informed consent agreement;
3. Subjects must be in good health, based upon the results of medical history, physical examination, electrocardiogram (ECG) and laboratory profiles of both blood and urine.;For the first cohort of the MAD study, in addition to the inclusion criteria as given above in D4, the following applies and/or overrides the corresponding exclusion criterion for the SAD study
1. Subjects who were administered a single dose of GRC 10963 in the SAD stage of the study may be enrolled.
2. Subjects who have turned 46 years of age since their participation in the SAD study may be enrolled.;Recruitment criteria of subjects for subsequent cohorts in the MAD stage may be equivalent to criteria of cohorts in SAD stage (after review of the results of the previous SAD and MAD cohort(s)).

Exclusion criteria

1. Subjects who smoke (subjects will have to be non-smokers for at least 6 months preceding screening);
2. Subjects with active presence or history of alcoholism or drug addiction;
3. Subject who had an operation in the within 3 months prior to the (first) dosing day;
4. Subjects who have used over-the-counter medication (including homeopathic medicines and vitamins), within 96 hours (h) prior to the dosing day, with the exception of paracetamol, which is allowed at the discretion of the PI;
5. Subjects who have used prescription medication within 2 weeks prior to the first dosing day;
6. Subjects who have participated in an investigational drug study within 3 months prior to the dosing day;
7. Subjects who have lost or donated >350 ml of blood within 12 weeks prior to the (first)

dosing day;
8. Subjects who test positive for hepatitis B, C or HIV;
9. Subjects who are considered unsuitable to participate in the study for any reason in the opinion of the PI.;For the first cohort of the MAD study, next to the exclusion criteria as given above in D5, the following applies and/or overrides the corresponding exclusion criterion for the SAD study:
1. Subjects who have participated in an investigational drug study except the SAD study of GRC 10963 within 3 months prior to the dosing day;
2. Subjects who have participated in the SAD stage of the study and whose exposure to GRC 10693 in terms of Cmax¬ and/or AUC0 * was more than two times the median value for the dose group, and/or whose terminal elimination half-life exceeded 52 hours.
3. Subjects who were administered a single dose of GRC 10963 in the SAD stage of the study may be enrolled with a Body Mass Index (BMI) <18.0 or >30.0 kg/m2;Exclusion criteria of subjects for subsequent cohorts in the MAD stage may be equivalent to criteria of cohorts in SAD stage (after review of the results of the previous SAD and MAD cohort(s)).

Study design

Design

Study type:	Observational invasive
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):	27-08-2008
Enrollment:	96
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GRC 10693

Generic name:	GRC 10693

Ethics review

Approved WMO Date:	06-08-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-08-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-11-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-11-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-11-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-12-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-01-2009
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-01-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-02-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-02-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2008-004239-39-NL
CCMO	NL23902.040.08