An eight-week double-blind, multi-center, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of aliskiren 75mg, 150mg and 300mg in elderly patients with essential hypertension when given a light meal

Published: 04-06-2008
Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON31913

Source
ToetsingOnline

Brief title
SPP2405

Condition

- Vascular hypertensive disorders

Synonym
hypertension, increased blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Farmaceutische industrie.

Intervention

Keyword: aliskiren, elderly, hypertension, light meal

Outcome measures

Primary outcome

Blood pressure (msSBP).

Secondary outcome

- Blood pressure (msSBP/msDBP).

- Lab evaluations.

- Physical examinations.

Study description

Background summary

This study is an eight-week double-blind, multi-center, randomized, placebo-controlled, paralel-group study to evaluate the efficacy and safety of aliskiren 75mg, 150mg and 300mg in elderly patients with essential hypertension when given with a light meal.

Study objective

The primary objective of the study is to confirm the efficacy of aliskiren 75 mg, 150 mg and 300 mg in patients with essential hypertension by testing the hypothesis of superior reduction in mean sitting systolic blood pressure (msSBP) from baseline to study end when compared to placebo.
The secundary objectives are:
- Evaluate the efficacy of aliskiren 75 mg, 150 mg and 300 mg in patients with essential hypertension by testing the hypothesis of superior reduction in mean

sitting diastolic blood pressure (msDBP) from baselineto study end when compared to placebo.
- Evaluate the effect of aliskiren 75 mg, 150 mg and 300 mg and placebo on the change from baseline in mean 24 hour ambulatory systolic blood pressure and ambulatory diastolic blood pressure in a subset of patients.
- Evaluate the effect of aliskiren 75 mg, 150 mg, 300 mg and placebo on the smoothness index, trough to peak ratio and morning surge of ambulatory systolic blood pressure and ambulatory diastolic blood pressure in a subset of patients.
- Evaluate the proportion of patients achieving blood pressure response rate as defined by msSBP < 140 mm Hg and/or a >/= 20 mm Hg decrease in msSBP from baseline to end of study.
- Evaluate thye safety and tolerability of aliskiren 75 mg, 150 mg and 300 mg.

Study design

Patiënts should comply to the inclusion and exclusion criteria as stated in the protocol. The study consists of a corestudy with a screening phase (wash-out phase of one week), a single blinded phase (placebo phase of two or three weeks) and a treatment phase (8 weeks of use of placebo, or aliskiren 75 mg, 150 mg or 300 mg).
Next to these study activities these patients will also be requested to participate in the ABPM sub study (Ambulatory Blood Pressure Monitoring). In this sub study patients will be requested to be hooked on the ABPM device one day before visit 3 and visit 7. Blood pressure will the be measured for 24 hours and on Visit 3 and Visit 7 these devices will be unhooked. The total study duration for each patient, inclusive of all phases, will be a minimum of approximately 70 days.

Intervention

Gedurende deze studie zullen de volgende parameters onderzocht worden:
Visite 1 (dag -21/-28): ICF; in-, exclusie criteria; medisch verleden; lichamelijk onderzoek; bloeddruk; hartslag; stoppen/omlaag titratie antihypertensie medicatie; rook verleden; labonderzoek; eventueel serum zwangerschapstest; ander medicatiegebruik; screenings log; IVRS handelingen.
Visite 2 (dag -14/-21): in-, exclusie criteria; bloeddruk; hartslag; ander medicatiegebruik; uitgeven studiemedicatie; IVRS handelingen.
Visite 201 (dag -7, zie protocol voor verdere specificaties van het nut van dit bezoek): in-, exclusie criteria; bloeddruk; hartslag; adverse events; ander medicatiegebruik; drug accountability; uitgeven studiemedicatie; IVRS handelingen.
Visite 3 (dag -1 tot 1): in-, exclusie criteria; lichamelijk onderzoek; lengte; gewicht; middelomvang; bloeddruk; hartslag; eventueel 24 uurs ABPM; labonderzoek; adverse events; ander medicatiegebruik; drug accountability; randomisatie; uitgeven studiemedicatie; IVRS handelingen.
Visite 4 (dag 14): bloeddruk; hartslag; labonderzoek; adverse events; ander

medicatiegebruik; drug accountability; uitgeven studiemedicatie; IVRS handelingen.
Visite 5 en 6 (respectievelijk dag 28 en 42): bloeddruk; hartslag; adverse events; ander medicatiegebruik; drug accountability; uitgeven studiemedicatie; IVRS handelingen.
Visite 7 (dag 56 tot 57): lichamelijk onderzoek; gewicht; bloeddruk; hartslag; eventueel 24 uurs ABPM; labonderzoek; adverse events; ander medicatiegebruik; drug accountability; IVRS handelingen; einde studie gegevens.
During this study the following interventions will be conducted:
Visit 1 (day -21/-28): ICF; in-, exclusion criteria; medical history; physical examination; blood pressure; pulse; discontinue/taper antihypertension medication; smoking history; lab evaluations; if applicable serum pregnancy test; concomitant medication; screenings log; IVRS.
Visit 2 (day -14/-21): in-, exclusion criteria; blood pressure; pulse; concomitant medication; dispensing study medication; IVRS
Visit 201 (day -7, see protocol for further specifications for the purpose of this visit): in-, exclusion criteria; blood pressure; pulse; adverse events; concomitant medication; drug accountability; dispensing study medication; IVRS
Visit 3 (day -1 till 1): in-, exclusion criteria; physical examination; length; weight; waistcircumference; blood pressure; pulse; if applicable 24 hour measurements; lab evaluations; adverse events; discontinue/taper antihypertension medication; drug accountability; randomization; concomitant medication; dispensing study medication; IVRS.
Visit 4 (day 14): blood pressure; pulse; lab evaluations; adverse events; concomitant medication; dispensing study medication; drug accountability; IVRS.
Visit 5 and 6 (respectively day 28 and 42): blood pressure; pulse; adverse events; concomitant medication; drug accountability; dispensing study medication; IVRS.
Visit 7 (day 56 till 57): physical examination; weight; blood pressure; pulse; if applicable 24 hour measurements; lab evaluations; adverse events; concomitant medication; drug accountability; IVRS; end of study information.

Study burden and risks

Potential inconveniences by participating in this trial might be that the patient needs to visit the general practitioner for 6 to 8 times and that his/her pulse/blood pressure will be measured 6 times. Also there will be a toital of 4 visits where a total maximum of 40 ml blood will be withdrawn. In case of blood samples taking there is a risk of some inconvenience and/or bruises and seldom an inflammation occurs.

Contacts

Public

Novartis

raapopseweg 1
6824 DP Arnhem
Nederland
Scientific
Novartis

raapopseweg 1
6824 DP Arnhem
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The mean sitting systolic blood pressure should be between 150 and 180 mm Hg mercury at randomisation (visit 3).

Exclusion criteria

Severe hypertension (mean sitting diastolic blood pressure above or equal 110 mm Hg and/or mean sitting systolic blood pressure above or equal 180 mm Hg.

Study design

Design

Study phase:	3
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):	31-07-2008
Enrollment:	124
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rasilez (150 mg)
Generic name:	Aliskiren (150 mg)
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rasilez (300 mg)
Generic name:	Aliskiren (300 mg)
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rasilez (75 mg)
Generic name:	Aliskiren (75 mg)
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	04-06-2008

Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	30-06-2008
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	08-09-2008
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

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	EUCTR2008-001305-42-NL
CCMO	NL23217.003.08